

1 Ramon Rossi Lopez – rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
2 Lopez McHugh LLP
100 Bayview Circle, Suite 5600
3 Newport Beach, California 92660
949-812-5771

4 Mark Stephen O'Connor (011029) – mark.oconnor@gknet.com
5 Gallagher & Kennedy, P.A.
2575 East Camelback Road
6 Phoenix, Arizona 85016-9225
602-530-8000

7 Julia Reed Zaic, Esq. – julia@hrzlaw.com
8 (California Bar Number 224671; admitted *pro hac vice*)
Laura Smith, Esq.
9 (California Bar Number 313879; admitted *pro hac vice*)
Heaviside Reed Zaic
10 312 Broadway, Suite 203
Laguna Beach, California 92660
11 949-715-5120

12 *Counsel for Plaintiffs*

13 UNITED STATES DISTRICT COURT

14 DISTRICT OF ARIZONA

15 In Re Bard IVC Filters Products
16 Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' CONTROVERTING
STATEMENT OF FACTS IN
OPPOSITION TO BARD'S MOTION
FOR SUMMARY JUDGMENT
REGARDING PREEMPTION**

(Assigned to the Honorable David G.
Campbell)

21
22 Plaintiffs submit this Controverting Statement of Facts in Support of their Motion
23 Opposition to Bard's Summary Judgment Regarding Preemption. Plaintiffs respond to
24 Bard's Statement of Facts ("SOF") allegations as follows:

25 1. Bard marketed several Inferior Vena Cava Filters (or "IVC Filters") for
26 permanent and retrievable placement, including the Recovery®, G2®, G2® Express,
27 G2®X, Eclipse™, Meridian®, and Denali® Filters. Decl. of Robert Carr ("Carr Decl.") at
28 ¶ 2, attached hereto as Exhibit A.

1 **Admit.**

2 2. These Filters are prescription IVC filters that were designed, manufactured,
3 packaged, labeled, and sold according to the terms of clearance by the Food and Drug
4 Administration (“FDA”) through the §510(k) process.

5 **Admit in part; deny in part. The Filters are intended to be sold according to**
6 **FDA clearance. However, Bard sold filters cleared as permanent with the knowledge**
7 **that they were being used as retrievable, despite the fact that retrievable clearance**
8 **had not been granted. Excerpts from Deposition Transcript of Daniel Orms (Aug.**
9 **16, 2016), attached hereto as Exhibit 1, at 43:21-44:21; see also FDA Contact Report**
10 **(Nov. 17, 2009), attached hereto as Exhibit 2.**

11 **I. The FDA Regulatory Clearance Process**

12 3. FDA is the federal agency responsible for regulating the manufacture, sale,
13 and distribution of medical devices, such as Bard’s IVC Filters. Decl. of John D. Van
14 Vleet (“Van Vleet Decl.”) at ¶ 6, attached hereto as Exhibit B.

15 **Admit.**

16 4. FDA derives its authority from the Food, Drug and Cosmetic Act
17 (“FDCA”), as amended by the Medical Device Amendments of 1976 (“MDA”). Ex. B,
18 Van Vleet Decl. at ¶ 6.

19 **Admit.**

20 5. The MDA requires that all medical devices, unless exempt by FDA
21 regulation, undergo FDA premarket review through either premarket notification
22 (“510(k)”) or premarket approval (“PMA”), which are intended to achieve FDA’s goal of
23 providing reasonable assurance of safety and effectiveness. FDA, *CDRH Preliminary*
24 *Internal Evaluations – Volume I: 510(k) Working Group Preliminary Report and*
25 *Recommendations*, at 22 (Aug. 2010), attached hereto as Exhibit C.

26 **Admit that the MDA provides two paths for a manufacturer to bring a**
27 **medical device to market and that 510(k) clearance and PMA are the two paths. To**
28 **the extent this allegation is construed to suggest that the FDA is certifying or**

1 **vouching for a device’s safety and efficacy, particularly through the 510(k) clearance**
 2 **process in which FDA expressly disclaims any such agency imprimatur, this**
 3 **allegation is denied.**

4 6. Class II devices, such as Bard’s IVC Filters, are required to obtain FDA
 5 clearance through the 510(k) process before the device can be marketed. Ex. B, Van
 6 Vleet Decl. at ¶ 8.

7 **Admit that Class II devices may be brought to market through 510(k)**
 8 **clearance. Deny any suggestion that such devices may only be brought to market**
 9 **through the 510(k) process.**

10 7. FDA will clear a 510(k) device only after it finds that the device is
 11 “substantially equivalent” to a “predicate” device. Ex. B, Van Vleet Decl. at ¶ 8.

12 **With the caveat that the FDA clearance is based upon its review of materials**
 13 **provided by the manufacturer and a determination based on those materials that the**
 14 **device is substantially equivalent to a previously-cleared or approved device, admit.**

15 8. A “predicate device” is either a device legally marketed prior to May 28,
 16 1976, for which PMA is not required, or a device reclassified from Class III to Class II or
 17 I, or a device which has been found substantially equivalent through the 510(k) process.
 18 21 C.F.R. § 807.92(a)(3).

19 **Admit.**

20 9. The MDA introduced but did not define the term “substantially equivalent,”
 21 so FDA was forced to look to the MDA’s “legislative history for guidance on how to
 22 interpret and apply the statutory standard established by the MDA.” Ex. C, at 23-24.

23 **Admit.**

24 10. FDA’s first formal articulation of the factors it would consider for
 25 substantial equivalence determinations was in FDA’s 1986 *Guidance on the CDRH*
 26 *Premarket Notification Review Program 6/30/86 (K86-3)* (issued June 30, 1986). Ex. C at
 27 24-25.

28 **Admit.**

1 11. The Safe Medical Devices Act of 1990 (“SMDA”) amended the MDA,
2 codifying FDA’s “substantial equivalence” review standard, and revising FDA’s authority
3 over medical devices. Ex. C, at 28.

4 **Admit.**

5 12. Under the statutory definition, a device is deemed substantially equivalent if
6 FDA determines that the subject device has the same intended use and the same
7 technological characteristics as the predicate device. Ex. B, Van Vleet Decl. at ¶ 8.

8 **Admit.**

9 13. If the device has the same intended use but different technological
10 characteristics, then FDA will only clear the device if those new technological
11 characteristics do not raise different questions of safety and effectiveness and the
12 manufacturer provides data that demonstrates that the new device is as safe and effective
13 as the predicate device. Ex. B, Van Vleet Decl. at ¶ 8.

14 **Admit.**

15 14. During FDA’s review of a 510(k) submission, FDA has the authority to
16 require additional information from the manufacturer if FDA deems it necessary to
17 determine substantial equivalence under 21 C.F.R. § 807.87(l), including clinical data. 21
18 U.S.C. § 360c(i)(1)(A)(ii). Ex. B, Van Vleet Decl. at ¶ 9.

19 **Admit.**

20 15. When clinical data is provided in the 510(k) submission it “should constitute
21 valid scientific evidence as defined in 21 C.F.R. § 860.7(c)(2) and must comply with the
22 Investigational Device Exemptions (IDE) regulations as applicable.” FDA Guidance, *The*
23 *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*,
24 at 23 (July 28, 2014), attached hereto as Exhibit D.

25 **Admit.**

26 16. “Only approximately eight percent of 510(k)s for non-*in-vitro*-diagnostic
27 devices contain clinical data, and only 11 percent of these 510(k)s reference a predicate
28 for which clinical data was provided. Less than one percent of non-*in-vitro*-diagnostic

1 510(k)s reference a clinical trial conducted under an approved Investigational Device
 2 Exemption application (IDE).” Ex. C, at 77.

3 **Objection, statement is based upon inadmissible hearsay. Subject to that**
 4 **objection, admit that the document so states.**

5 17. If the device manufacturer does not comply with FDA’s demand for
 6 additional information, then the submission is deemed withdrawn under 21 C.F.R. §
 7 807.87(l). Ex. B, Van Vleet Decl. at ¶ 9.

8 **Admit.**

9 18. If FDA determines that the device is substantially equivalent, then it will
 10 issue a letter clearing the device to be marketed. Ex. B, Van Vleet Decl. at ¶ 9.

11 **Admit.**

12 19. FDA stated in its 2017 Memorandum: “Although the 510(k) process
 13 involves a comparison of a new device to a predicate device rather than an independent
 14 demonstration of the new device’s safety and effectiveness . . . , in all these cases FDA’s
 15 review process reflects a determination of the level of control necessary to provide a
 16 ‘reasonable assurance of safety and effectiveness.’” FDA Memorandum, *Public Health*
 17 *Interests and First Amendment Considerations Related to Manufacturer Communications*
 18 *Regarding Unapproved Uses of Approved or Cleared Medical Products*, at 44-45
 19 (January 2017), attached hereto as Exhibit E.

20 **Objection, statement is based upon inadmissible hearsay. In addition, this is**
 21 **based on a 2017 document and there is no admissible evidence establishing that this**
 22 **document reflects FDA thinking at the time it acted on Bard’s various clearance**
 23 **applications. Subject to these objections, admit that the document so states.**

24 **II. Class II Devices and “Special Controls”**

25 20. The “MDA established a three-tiered regulatory system with safety and
 26 effectiveness requirements applicable to all medical devices, and a classification scheme
 27 requiring that devices be placed into one of three” regulatory control categories: Class I,
 28 II, or III. Ex. C, at 21; Ex. B, Van Vleet Decl. at ¶ 7.

1 **Admit that the document so states.**

2 21. According to FDA, device classification depends upon “the degree of
3 regulation necessary to provide reasonable assurance of [the device’s] safety and
4 effectiveness. The class into which a device is placed determines the requirements that a
5 medical device manufacturer must meet prior to distributing a device in interstate
6 commerce.” Ex. D, at 2.

7 **Admit that the document so states.**

8 22. FDA classifies Bard’s IVC Filters as Class II devices. Ex. B, Van Vleet
9 Decl. at ¶ 7.

10 **Admit.**

11 23. Class II devices are defined as “Devices for which general controls, by
12 themselves, are insufficient to provide reasonable assurance of the safety and
13 effectiveness of the device, and for which there is sufficient information to establish
14 special controls to provide such assurance.” Ex. D, at 2.

15 **Admit.**

16 24. The original 1976 definition of Class II devices in the MDA “identified
17 performance standards rather than special controls as the mechanism by which FDA could
18 establish reasonable assurance of safety and effectiveness.” Ex. D, at 2 n.2.

19 **Admit.**

20 25. The SMDA amended the MDA, adding “special controls” to the definition
21 of Class II devices, “which can include the promulgation of performance standards as well
22 as postmarket surveillance, patient registries, development and dissemination of guidance
23 documents, and other appropriate actions as FDA deems necessary to provide such
24 assurance. This authority gave FDA more flexibility in identifying the controls necessary
25 to provide reasonable assurance of the safety and effectiveness of class II devices.” Ex. C,
26 at 28.

27 **Deny. The SMDA amended the MDA by replacing “Performance Standards”**
28 **513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) with “Special Controls” (513(a)(1)(B) (21**

1 **U.S.C. 360c(a)(1)(B)). The amended section provides examples of special controls of**
 2 **which performance standards effectively became one of many. 21 U.S.C.**
 3 **360c(a)(1)(B). Special controls replaced performance standards as a less**
 4 **administratively burdensome means for the agency to conduct its review. Excerpts**
 5 **from (Second) Supplemental Report of David A. Kessler, M.D., attached hereto as**
 6 **Exhibit 3,¹ at 14.**

7 26. According to FDA, “[s]pecial controls are regulatory requirements for class
 8 II devices.”² Earlier this year, FDA reiterated that “[s]pecial controls are device-specific.”
 9 Ex. E, at 41 n.122.

10 **Admit that special controls can be device-specific. Deny that any of the special**
 11 **controls applicable to IVC filters are specific to Bard IVC filters or retrievable filters**
 12 **generally. See Excerpts from Deposition Transcript of Robert Carr (June 6, 2017),**
 13 **attached hereto as Exhibit 5, at 31-33.**

14 27. Bard’s IVC Filters, as Class II devices, are subject to the general controls
 15 under the MDA and the specific special controls for IVC Filters found in 21 C.F.R. §
 16 870.3375. Ex. B, Van Vleet Decl. at ¶ 7.

17 **Admit that special controls for IVC filters are found at 21 C.F.R. § 870.3375.**
 18 **Deny that any of the special controls applicable to IVC filters are specific to Bard**
 19 **IVC filters or retrievable filters generally. See Ex. 3 at 14-19; Ex. 5 at 31-33.**

20 28. FDA’s IVC Filter regulation, 21 C.F.R. § 870.3375, required Bard to
 21 comply with the following in each IVC Filter 510(k) submission: ISO 10993 *Biological*
 22 *Evaluation of Medical Devices Part I: Evaluation and Testing*; FDA’s 510(k) *Sterility*
 23 *Review Guidance and Revision of 2/12/90 (K90-1)*; and FDA’s *Guidance for*
 24

25
 26 ¹ This report is incorporated by reference in the Declaration of David A. Kessler (Aug. 28,
 27 2017), attached hereto as Ex. 4, at ¶ 5.

28 ² FDA, Regulatory Controls (Medical Devices),
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm> (last updated June 26, 2014).

1 *Cardiovascular Intravascular Filter 510(k) Submissions* (November 26, 1999). Ex. B,
 2 Van Vleet Decl. at ¶ 7.

3 **Admit that 21 C.F.R. § 870.3375 identifies special controls for IVC filters.**
 4 **Deny that compliance with the listed documents is required. There is no language in**
 5 **this C.F.R. requiring compliance with the items listed; at least one document listed**
 6 **(FDA’s *Guidance for Cardiovascular Intravascular Filter 510(k) Submissions***
 7 **(November 26, 1999)) clearly states it is a guidance document which “describes a**
 8 **means by which cardiovascular intravascular filter devices may comply with the**
 9 **requirement of special controls for Class II devices.” It also states that the**
 10 **“document is intended to provide guidance. It represents the Agency’s current**
 11 **thinking on the above. It does not create or confer any rights for or on any person**
 12 **and does not operate to bind FDA or the public. An alternative approach may be**
 13 **used if such approach satisfies the requirements of the applicable statute,**
 14 **regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-00034595); see also Ex. 5 at**
 15 **31-33.**

16 29. The FDA’s *Guidance for IVC Filter 510(k) Submissions* is a device-specific
 17 guidance document. FDA’s *Guidance for Cardiovascular Intravascular Filter 510(k)*
 18 *Submissions* (November 26, 1999) [hereinafter “Filter Guidance”], attached hereto as
 19 Exhibit F.

20 **Deny. While the Guidance applies to IVC filters, it is not specific to Bard IVC**
 21 **filters or retrievable IVC filters. See Bard SOF Ex. F at 3 (noting that document**
 22 **applies to filters generally); see also Ex. 5 at 31-33.**

23 30. Using special controls, “FDA has issued many device-specific guidance
 24 documents that clarify the data that should be included in 510(k)s for particular device
 25 types.” Exhibit D, at 6.

26 **Objection, statement is based upon inadmissible hearsay. Subject to that**
 27 **objection, admit the document so states. Deny that the quoted statement relates to**
 28 **special controls.**

1 31. The Filter Guidance required that Bard perform biocompatibility testing in
2 accordance with the provisions in ISO 10993 for implantable, blood-clotting devices. Ex.
3 F, at 3.

4 **Deny.** Section III of the Guidance states that such tests “should be conducted
5 in accordance with FDA document ‘Use of International Standard ISO-10993,
6 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.’” See Bard
7 SOF Ex. F at 3 (BPV-17-01-00034597) (emphasis added). The document further
8 states that it is designed to provide mere “guidance” to the manufacturer and that a
9 manufacturer may use an “alternative approach” provided that “such approach
10 satisfies the requirements of the applicable statute, regulations, or both.” *Id.* at 1
11 (BPV-17-01-00034595) n.1.

12 32. The Filter Guidance further required Bard to perform pre-clinical testing
13 that adequately addressed the following issues related to the filter design: simulated
14 deployment, introducer/sheath suitability, clot trapping ability, filter fracture, caval
15 perforation/filter migration, thrombogenicity, and MRI compatibility. Ex. F, at 3-5.

16 **Deny.** The Guidance does not require particular pre-clinical testing. The
17 Guidance states, “Below is an outline of the general issues that need to be addressed
18 when seeking premarket clearance for a filter. It is the submitter's responsibility to
19 conduct testing which adequately addresses the concerns outlined below as well as
20 any others which may arise due to the unique design of the given device. The goal of
21 this outline is to identify the objective(s) of the pre-clinical test. Test protocols and
22 acceptance criteria for these tests are the responsibility of the submitter.” Bard SOF
23 Ex. F at 1 (BPV-17-01-00034595); *see also* Ex. 5 at 51:15-17.

24 33. The Filter Guidance warned that the “necessary array of tests for a particular
25 filter will depend, in part, on the specific design,” and that additional pre-clinical testing
26 may be “necessary to qualify all filters/designs.” Ex. F, at 2.

27 **Admit that Ex. F states this. Dispute that this was a “warning” to**
28 **manufacturers.**

1 34. “The degree to which a proposed device is similar to a currently marketed
2 filter will indicate the level of testing necessary, i.e., whether the design characteristics
3 can be assessed via *in vitro* bench testing, in vivo animal testing, clinical testing or some
4 combination of all three.” Ex. F, at 2.

5 **Admit.**

6 35. The Filter Guidance warned that human clinical investigations could be
7 necessary for new IVC filter designs or even for modified filter designs. Ex. F, at 5.

8 **Admit that Ex. F states this. Dispute that this was a “warning” to**
9 **manufacturers.**

10 36. The Filter Guidance further identified specific complications that Bard had
11 to analyze during its clinical investigation. Ex. F, at 5-9.

12 **Deny. The Guidance document only recommended certain complications that**
13 **should be analyzed for if a clinical investigation was deemed necessary, and the**
14 **document is not specific to Bard or retrievable filters.**

15 37. The Filter Guidance also required Bard to include specific text in its labeling
16 and follow specific label formatting. Ex. F, at 9-10.

17 **Deny. The textual labeling language proposed was a recommendation to Bard**
18 **that it “should” include such language in its labeling. Bard SOF Ex. F at 10 (BPV-**
19 **17-01-00034604). The language did not mandate a requirement for Bard to use**
20 **specific language. In addition, Bard frequently and successfully negotiated with FDA**
21 **on changes to FDA-proposed language in labels. See, e.g., Bard SOF at ¶¶ 92, 681,**
22 **771, 775, 780.**

23 38. Bard is prohibited from unilateral labeling changes that significantly impact
24 safety and effectiveness without first submitting a new 510(k). See FDA Guidance, *FDA*
25 *Deciding When to Submit a 510(k) for a Change to an Existing Device* (K97-1), at 9-12
26 (January 10, 1997), attached hereto as Exhibit G.

27 **Deny. The cited pages of Exhibit G are suggestions from FDA concerning best**
28 **practices for reducing unnecessary 510(k) submissions. Additionally, FDA allows**

1 **manufacturers “the flexibility to improve their labeling to insure maximum safe and**
 2 **effective use of their devices.” Bard SOF Ex. G at 12.**

3 39. “[T]he 510(k) program has changed significantly since its inception....
 4 Through various statutory and regulatory modifications over time, it has become a
 5 multifaceted premarket review process that is expected to assure that cleared devices,
 6 subject to general and applicable special controls, provide reasonable assurance of safety
 7 and effectiveness, and to facilitate innovation in the medical device industry.” Ex. C, at
 8 28.

9 **Objection, statement is based upon inadmissible hearsay. Subject to that**
 10 **objection, deny. This language does not appear on page 28 of Exhibit C. Admit that**
 11 **the document states this on page 34. Compare Bard SOF Ex. C at 28 with Bard SOF**
 12 **Ex. C at 34.**

13 **III. Recovery® Filter:**

14 **A. Recovery Filter for Permanent Indication (K022236)**

15 40. On November 1, 1999, prior to Bard’s acquisition of NMT’s line of filter
 16 products, NMT submitted a Special 510(k) seeking clearance for the Recovery Filter
 17 System. Ex. A, Carr Decl. at ¶ 5.

18 **Admit.**

19 41. This filter modified NMT’s previously cleared predicate device, the Simon
 20 Nitinol Filter/Straight Line System. Ex. A, Carr Decl. at ¶ 5.

21 **Admit.**

22 42. NMT sought FDA clearance for an expanded indication allowing retrieval
 23 of the filter if it was misplaced or malpositioned. Ex. A, Carr Decl. at ¶ 5.

24 **Admit.**

25 43. On December 10, 1999, the FDA sent a letter to NMT, stating that the
 26 Special 510(k) submission had “major deficiencies,” in that clinical data would be
 27 required to determine whether the new device was substantially equivalent to the predicate
 28 devices. Ex. A, Carr Decl. at ¶ 6.

1 **Admit.**

2 44. The FDA therefore considered NMT's submission withdrawn and deleted
3 from the FDA system. Ex. A, Carr Decl. at ¶ 6.

4 **Admit.**

5 45. On February 10, 2000, NMT and FDA met to discuss the need for a clinical
6 trial, but no decision was reached. Ex. A, Carr Decl. at ¶ 7.

7 **Admit.**

8 46. FDA reaffirmed that “clinical data would be required to support a future
9 510k submission during a February 29, 2000 telephone conference. Ex. A, Carr Decl. at
10 ¶ 7.

11 **Objection, statement is based upon inadmissible hearsay. Subject to that**
12 **objection, admit.**

13 47. FDA required clinical data before it would clear a retrievability indication
14 because the FDA was concerned about possible acute complications, including acute
15 migration, fracture, occlusion, and cava puncture. Ex. A, Carr Decl. at ¶ 7.

16 **Objection, statement is based upon inadmissible hearsay. Subject to that**
17 **objection, admit.**

18 48. Before Bard acquired NMT's entire IVC filter line of products in 2001, a
19 clinical study was underway for the Recovery Filter by Dr. Murray Asch in Toronto,
20 Canada on behalf of NMT and Bard. Ex. A, Carr Decl. at ¶ 7.

21 **Deny. The Asch Study was not related to safety and efficacy of long term use**
22 **of the filter. It was related only to the filter's retrievability. Excerpts from**
23 **Deposition Transcript of Murray Asch (May 2, 2016), attached hereto as Exhibit 6,**
24 **at 19:2-20:17.**

25 49. On July 10, 2002, IMPRA, a subsidiary of Bard, submitted its Special
26 510(k) for the Recovery Filter for a permanent indication only. Ex. A, Carr Decl. at ¶ 8.

27 **Admit.**

1 50. IMPRA's Recovery® 510(k) submission submitted a battery of *in vitro*
2 testing BPV (and NMT) had conducted on the Recovery® Filter, including clot trapping
3 efficiency, migration, weld integrity, hook strength, corrosion/fatigue testing, radial
4 strength, simulated use, and more. Ex. A, Carr Decl. at ¶ 8.

5 **Objection. Vague as to the term “battery.” Subject to that objection, admit**
6 **that the submission contained testing conducted by BPV and NMT.**

7 51. BPV's bench testing was performed in conformance with the FDA guidance
8 document: “Guidance for Cardiovascular Intravascular Filter 510(k) Submission.” Ex. A,
9 Carr Decl. at ¶ 8.

10 **Deny to the extent it is suggested that the Guidance document required any**
11 **specific testing or test protocols. See Excerpts from Trial Testimony of Suzanne**
12 **Parisian, *Phillips v. Austin*, attached hereto as Exhibit 7, at 139:13-21 (noting that the**
13 **FDA Guidance document is “not a cookbook” and merely encourages manufacturers**
14 **to evaluate certain things).**

15 52. BPV's design verification for the modifications and the manufacturing
16 facility for the Recovery® filter conformed to the design control requirements of 21 CFR
17 § 820.30. Ex. A, Carr Decl. at ¶ 8.

18 **Admit that Bard submitted declarations stating conformance with design**
19 **controls. Deny as to the existence of specific design controls contained in 21 C.F.R. §**
20 **820.30 as to IVC filters. The code section only states that manufacturers shall**
21 **establish their own procedures and plans, not that the FDA has promulgated any**
22 **design controls for individual devices. See 21 C.F.R. § 820.30.**

23 53. The Recovery® 510(k) submission included the proposed labeling for the
24 Recovery® Filter in conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 8.

25 **Admit the Recovery 510(k) contained a copy of the proposed IFU for the**
26 **Recovery device and schematics of “pouches” containing the delivery system. Deny**
27 **that 510(k) contained a “labeling” which includes promotional materials,**
28

1 **communications, etc. Excerpts from Deposition Transcript of Christine Brauer (Aug.**
2 **20, 2017), attached hereto as Exhibit 8, at 18:11-22.**

3 54. The Recovery® 510(k) submission also included a summary of the safety
4 and effectiveness information upon which a substantial equivalence determination could
5 be based as required by the Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex.
6 A, Carr Decl. at ¶ 8.

7 **Admit.**

8 55. The Recovery® 510(k) submission further included clinical data from the
9 Dr. Murray Asch clinical study conducted in Toronto to support the determination of
10 substantial equivalence as a permanent filter. Ex. A, Carr Decl. at ¶ 8.

11 **Admit the Recovery filter submission for permanent indication contained a**
12 **summary and Bard's description of clinical data from the Asch study. Deny that**
13 **Bard provided actual clinical data in its Recovery filter submission for permanent**
14 **indication. See Bard SOF Ex. A at Ex. 6 (BPV-17-01-00057981-86).**

15 56. On August 5, 2002, the FDA sent IMPRA a letter requiring additional
16 information to complete the review of IMPRA's submission. Ex. A, Carr Decl. at ¶ 9.

17 **Admit.**

18 57. The FDA prohibited IMPRA from marketing its Recovery® filter until it
19 had provided the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶
20 9.

21 **Admit.**

22 58. If IMPRA failed to respond within 30 days, the FDA would have treated this
23 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 9.

24 **Admit.**

25 59. The FDA's August 5, 2002 letter required responses to 17 agency-posed
26 questions regarding clinical testing, bench performance testing, biocompatibility, and
27 administrative elements. Ex. A, Carr Decl. at ¶ 9.

28 **Admit.**

1 60. Among other things, the FDA asked questions about IMPRA's root cause
2 analysis of filter tilting, and whether tilting of the Recovery® Filter affected its safety and
3 effectiveness. Ex. A, Carr Decl. at ¶ 9.

4 **Admit.**

5 61. The FDA also sought information regarding issues such as integrity
6 inspections of the filter and fatigue testing of its welds and hooks. Ex. A, Carr Decl. at ¶
7 9.

8 **Admit.**

9 62. On August 12, 2002, IMPRA and the FDA held a teleconference to discuss
10 the FDA's demand for additional information. Ex. A, Carr Decl. at ¶ 10.

11 **Objection, statement is based upon inadmissible hearsay and lacks**
12 **foundation. Furthermore, statement misstates evidence as to FDA's "demand for**
13 **additional information." The cited exhibit is a memorandum which purports to**
14 **address a teleconference with FDA representatives on August 12, 2002. The**
15 **memorandum reflects the FDA's requests for additional information. Subject to**
16 **these objections, admit.**

17 63. On August 30, 2002, IMPRA provided the FDA with the required additional
18 information. Ex. A, Carr Decl. at ¶ 11.

19 **Admit.**

20 64. IMPRA answered each question/request in order, including additional data
21 or explanation as needed, as well as test results and other supporting materials. Ex. A,
22 Carr Decl. at ¶ 11.

23 **Admit IMPRA provided additional information and data. Deny that all data**
24 **was directly from testing of the Recovery device; some data was referenced and**
25 **incorporated from previous Bard 510(k) applications, specifically the Simon Nitinol**
26 **Filter application in 1990 (K894703). Bard SOF Ex. A at ¶ 11 and at Ex. 10 (BPV-17-**
27 **01-00057770).**

65. In particular, IMPRA responded to the FDA's safety and effectiveness concerns about root cause analysis of the Recovery® Filter tilting and IMPRA's clinical experience with such tilting. Ex. A, Carr Decl. at ¶ 11.

Admit IMPRA responded to the FDA's inquiry related to tilting. Deny the FDA's review was for independent establishment of safety and effectiveness specific to the Recovery filter; the review was for substantial equivalence to the predicate. Ex. 3 at ¶ 25-26.

66. On October 1, 2002 and October 3, 2002, IMPRA and the FDA held additional teleconferences to discuss the additional information required by the FDA. Ex. A, Carr Decl. at ¶ 12.

Admit.

67. IMPRA provided the FDA with further clarification about its responses. Ex. A, Carr Decl. at ¶ 12.

Admit.

68. On October 4, 2002, the FDA sent IMPRA a second letter requiring still more information. Ex. A, Carr Decl. at ¶ 13.

Admit. However, this "requirement" was based upon Bard not "completely responding to the deficiencies listed in [FDA's] August 5, 2002 letter." Bard SOF Ex. A at Ex. 10 (BPV-17-01-00057740).

69. The FDA again prohibited IMPRA from marketing its Recovery® filter until it had provided the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 13.

Admit.³

³ Bard repeatedly remarks that the FDA refused to allow marketing of its devices until information was provided and that if Bard did not respond, the submission would be deemed withdrawn. This is neither remarkable nor relevant. If a manufacturer fails to provide the FDA with information it deems necessary to make a determination of substantial similarity, then the FDA cannot do its job and cannot confer regulatory clearance of the product to market.

1 70. If IMPRA failed to respond within 30 days, the FDA would have treated this
2 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 13.

3 **Admit.**

4 71. The FDA required justification for IMPRA having not tested the filter's
5 efficacy in capturing 2-4 mm clots, and required IMPRA to provide "objective and
6 quantifiable data" to demonstrate that the device design was sufficiently similar to the
7 filters tested in the literature (Question 1). Ex. A, Carr Decl. at ¶ 13.

8 **Admit.**

9 72. The FDA also required IMPRA to detail its radial strength testing and its
10 compliance with the caval perforation/filter migration testing requirement of the Guidance
11 for Cardiovascular Intravascular Filter 510(k) Submissions (Question 2). Ex. A, Carr
12 Decl. at ¶ 13.

13 **Admit that the FDA requested that Bard discuss its radial strength testing.**
14 **Deny that the Guidance document contained "required" testing. See Excerpts from**
15 **Deposition Transcript of Kay Fuller (Jan. 11, 2016), attached hereto as Exhibit 9, at**
16 **53:7-56:4; Ex. 3 at ¶¶ 38, 45; Ex. 5 at 51:15-17.**

17 73. The FDA further required IMPRA to revise the filter's instructions for use
18 ("IFU") and labeling to state that the Recovery® Filter was indicated for permanent
19 placement only (Question 3). Ex. A, Carr Decl. at ¶ 13.

20 **Admit that the FDA requested revision of IFU. Deny that the FDA required**
21 **any particular language. Bard SOF Ex. A at Ex. 10 (BPV-17-01-00057741).**

22 74. On October 25, 2002, IMPRA responded to the FDA's October 4, 2002
23 demand by providing the required additional information. Ex. A, Carr Decl. at ¶ 14.

24 **Admit.**

25 75. In response to FDA's demand (Question 1), IMPRA justified not separately
26 testing for 2-4mm clot trapping ability by comparing the design of the Recovery® Filter
27 to five equivalent filters already tested in the literature, as determined by comparative
28 dimensional measurements. Ex. A, Carr Decl. at ¶ 14.

1 **Admit.**

2 76. In response to FDA's demand (Question 2), IMPRA provided an in-depth
3 explanation of compliance with the requirements of FDA's Guidance for Cardiovascular
4 Intravascular Filter 510(k) Submissions concerning radial strength and caval
5 perforation/filter migration testing. Ex. A, Carr Decl. at ¶ 14.

6 **Admit IMPRA provided an explanation. Deny to the extent that the Guidance**
7 **document contains specific requirements for device clearance. Ex. 3 at ¶¶ 37-45; 9 at**
8 **53:7-56:4.**

9 77. In response to FDA's demand (Question 3), IMPRA included the required
10 revisions to the Recovery® Filter's indication statement in the IFU and labeling. Ex. A,
11 Carr Decl. at ¶ 14.

12 **Admit.**

13 78. On November 27, 2002, the FDA cleared the Recovery® Filter, finding it as
14 safe and effective as, and therefore substantially equivalent to, the predicate device for
15 permanent indication, subject to the general controls and special controls of the FDCA.
16 Ex. A, Carr Decl. at ¶ 15.

17 **Admit.**

18 79. The FDA had reviewed all of the data originally submitted by IMPRA, and
19 the two sets of additional information the FDA had required by letter. Ex. A, Carr Decl.
20 at ¶ 15.

21 **Admit.**

22 80. Because the FDA determined there was a reasonable likelihood that this
23 device would be used off-label for a retrievable indication, and that such use could cause
24 harm, the FDA limited the substantial equivalence finding and, pursuant to 21 U.S.C. §
25 360c(i)(1)(E), required IMPRA to include specific language in the Recovery® Filter's
26 labeling and promotional materials stating: "The safety and effectiveness of the Recovery
27 Filter for use as a retrievable or temporary filter have not been established." Ex. A, Carr
28 Decl. at ¶ 15.

1 **Admit.**

2 **B. Recovery® Filter for Percutaneous Retrieval (K031328)**

3 81. In November 2002 and December 2002, responsibility for Bard's filter line
4 of products shifted to another division of Bard, moving from IMPRA to BPV. IMPRA
5 had no further involvement. Ex. A, Carr Decl. at ¶ 16.

6 **Admit.**

7 82. On December 17, 2002, BPV sent the FDA a letter requesting a meeting
8 with the FDA to propose changes to BPV's labeling and IFU for the Recovery® Filter.
9 Ex. A, Carr Decl. at ¶ 17.

10 **Admit.**

11 83. BPV requested this meeting in preparation for its 510(k) filing for the
12 Recovery® Filter to remove the FDA-imposed labeling limitation regarding percutaneous
13 retrieval. Ex. A, Carr Decl. at ¶ 17.

14 **Admit.**

15 84. BPV attached numerous materials to the letter in advance of the meeting,
16 including proposed labeling and IFU amendments, results of animal testing, results of Dr.
17 Asch's clinical study, and other materials. Ex. A, Carr Decl. at ¶ 17.

18 **Objection. Assumes facts not in evidence. Subject to that objection, can**
19 **neither admit nor deny as no attachments to the referenced letter are attached.**

20 85. On January 14, 2003, BPV and the FDA met to discuss BPV's proposed
21 changes and the materials submitted with BPV's December 17, 2002 letter. Ex. A, Carr
22 Decl. at ¶ 18.

23 **Admit.**

24 86. The FDA reviewed the *in-vivo* animal testing and the clinical testing of the
25 Recovery® Filter and raised questions regarding the animal histology and whether
26 additional clinical data was available, which BPV agreed to address (Question 1). Ex. A,
27 Carr Decl. at ¶ 18.

28 **Admit.**

1 87. The FDA also reviewed the IFU and labeling and raised questions regarding
2 the proposed amendments. The FDA stated that BPV's proposed precaution statement
3 about thrombus should be raised to a warning and included in the warning section, which
4 BPV agreed to address in the 510(k) (Question 2). Ex. A, Carr Decl. at ¶ 18.

5 **Admit.**

6 88. The FDA stated that the IFU should be revised to include removal
7 techniques developed during BPV's *in-vivo* animal and clinical testing, which BPV agreed
8 to address in the 510(k) (Question 2). Ex. A, Carr Decl. at ¶ 18.

9 **Admit.**

10 89. On January 31, 2003, BPV and the FDA had a follow-up telephone
11 conference. Ex. A, Carr Decl. at ¶ 19.

12 **Admit.**

13 90. The FDA stated that BPV "had supplied good supportive information that
14 provided the agency with an appropriate level of comfort." Ex. A, Carr Decl. at ¶ 19.

15 **Objection, statement contains inadmissible hearsay as to what the FDA is**
16 **reported to have said. Subject to that objection, admit that Bard SOF Ex. A at Ex. 14**
17 **(BPV-17-01-00055232-36) makes this representation.**

18 91. During the telephone conference, the FDA raised additional concerns
19 regarding, among other things, the proposed labeling. Ex. A, Carr Decl. at ¶ 19.

20 **Admit.**

21 92. The FDA required that specific language be added to the Indication section
22 providing that the Recovery® Filter could be removed only within a specified time period
23 after insertion. BPV agreed to draft proposed language for FDA's review. Ex. A, Carr
24 Decl. at ¶ 19.

25 **Objection, statement contains inadmissible hearsay as to what the FDA is**
26 **reported to have said. Subject to that objection, admit that Bard SOF Ex. A at Ex. 14**
27 **(BPV-17-01-00055232-36) makes this representation. The FDA negotiated with Bard**
28 **regarding language about data it had for time to removal or that the FDA presented**

1 **Bard with specific language and required to adopt. The document states: “We**
 2 **believe there should be a time specified, and it should be based on the mean time for**
 3 **which data are currently available, as stated before. We would be willing to consider**
 4 **alternate approaches.....[T]he labeling for the retrieval time is probably an issue that**
 5 **will need to be decided at a higher level, after deliberation. Dr. Harvey recommend**
 6 **that you submit your best proposal given the thoughts we have provided to date and**
 7 **we will work on revisions during the review process...” Bard SOF Ex. A at Ex 14**
 8 **(BPV-17-01-00055232-36).**

9 93. The FDA also required that the precaution statement about thrombus not
 10 only be elevated to a warning but also be bolded and italicized, which BPV agreed to
 11 address in the 510(k). Ex. A, Carr Decl. at ¶ 19.

12 **Objection, statement is based upon inadmissible hearsay as to what the FDA is**
 13 **reported to have said. Admit that Bard SOF Ex. A at Ex 14 (BPV-17-01-00055232-**
 14 **36) makes this representation.**

15 94. Between March 14 and March 21, 2003, BPV and the FDA exchanged
 16 emails about the proposed changes to the labeling of the Recovery® Filter. Ex. A, Carr
 17 Decl. at ¶ 20.

18 **Admit.**

19 95. The FDA reviewer stated that “it is likely that the label will need revision
 20 regarding the time to removal” and should specify a time for removal of the filter. Ex. A,
 21 Carr Decl. at ¶ 20.

22 **Admit.**

23 96. BPV emailed revised proposed labeling for FDA review, but the FDA
 24 responded that the proposed labeling regarding the retrieval time would probably be
 25 decided at a higher level, and that BPV should submit its 510(k) application based on the
 26 FDA’s input to date. Ex. A, Carr Decl. at ¶ 20.

27 **Admit.**
 28

1 97. The FDA assured BPV that it would “work on revisions during the review
2 process.” Ex. A, Carr Decl. at ¶ 20.

3 **Admit.**

4 98. On April 25, 2003, BPV submitted an Abbreviated 510(k) for percutaneous
5 retrieval of the Recovery® Filter in order to remove the labeling restriction and add
6 specific instructions for removal of the Recovery® Filter. Ex. A, Carr Decl. at ¶ 21.

7 **Admit.**

8 99. The proposed changes amended the indications, labeling, and IFU. BPV did
9 not propose any design changes, and its 510(k) emphasized that the proposed changes did
10 not change the original intended use of the cleared Recovery Filter. Ex. A, Carr Decl. at ¶
11 21.

12 **Admit.**

13 100. The 510(k) submission included and was supported by full results of BPV’s
14 animal study and the Asch clinical study that BPV previously shared with the FDA, as
15 well as by testing materials from those studies. Ex. A, Carr Decl. at ¶ 21.

16 **Admit the Recovery 510(k) submission for retrievability included pre-clinical**
17 **data from animal studies. Deny the application contained the full results of the**
18 **clinical study; it contained procedure notes and some follow up notes as well as**
19 **summaries drafted by Bard.**

20 101. The 510(k) also included proposed amendments to the labeling and IFU in
21 conformance with 21 CFR § 807.87(e), which included the changes that the FDA required
22 during its previous correspondence with BPV. Ex. A, Carr Decl. at ¶ 21.

23 **Admit.**

24 102. The submission also included a summary of the safety and effectiveness
25 information upon which a substantial equivalence determination could be based as
26 required by the Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr
27 Decl. at ¶ 21.

28 **Admit.**

1 103. On July 1, 2003, the FDA sent BPV an email requiring that BPV include a
2 “clinical experience” section in the Recovery® Filter IFU discussing the clinical results
3 from the Asch study. Ex. A, Carr Decl. at ¶ 22.

4 **Admit that the FDA requested a draft of a “clinical experience” section in the**
5 **IFU regarding clinical experience because a “clinical study” section could not be**
6 **considered because no formal study was undertaken for the device. Bard SOF Ex. A**
7 **at Ex. 15 (BPV-17-01-00054093).**

8 104. The FDA assured BPV that it would “provide comment” on the drafted
9 language. Ex. A, Carr Decl. at ¶ 22.

10 **Admit.**

11 105. On July 2, 2003, the FDA sent BPV an email demanding clarification
12 regarding whether the testing reported in the Recovery® Filter 510(k) submission
13 involved sterilized samples. Ex. A, Carr Decl. at ¶ 23.

14 **Admit. Deny that information regarding sterilized samples was provided.**
15 **Bard SOF Ex. A at Ex. 16.**

16 106. The FDA also inquired as to whether the tests were performed after aging.
17 Later that same day, BPV responded to the FDA that shelf life testing was done on the
18 devices in the submission, and FDA requested this shelf life data. Ex. A, Carr Decl. at
19 ¶ 23.

20 **Admit Bard provided information regarding shelf life data. Deny that**
21 **information regarding sterilized samples was provided; testing on sterilized**
22 **Recovery devices was not conducted. Bard SOF Ex. A at Ex. 16; Excerpts from**
23 **Deposition of Kay Fuller (Nov. 9, 2010), attached hereto as Exhibit 10, at 26:2-31:13;**
24 **Ex. 9 at 127:4-128:7, 223:15- 223:23.**

25 107. On July 8, 2003, BPV faxed all of the required information to the FDA,
26 including the stability protocols, stability test reports, stability product adoption/rationale,
27 and accelerated aging protocols. Ex. A, Carr Decl. at ¶ 24.

1 **Deny.** The FDA also requested bench testing relating to sterilized samples,
2 **which were not included. Bard SOF Ex. A at Ex. 16**
3 **(FDA_PRODUCTION_00001291).**

4 108. On July 22, 2003, an internal FDA memorandum extensively reviewed the
5 animal testing submitted with BPV's Recovery® Filter 510(k). Ex. A, Carr Decl. at ¶ 25.

6 **Object to the term “extensively” as vague. Subject to that objection, admit**
7 **that the FDA reviewed the animal testing.**

8 109. The FDA stated that BPV “has provided the clarification and additional
9 descriptions suggested at that [January 14, 2003] meeting by providing the pathology
10 reports and figures of the histology and postmortem tissues with legends.” Ex. A, Carr
11 Decl. at ¶ 25.

12 **Admit.**

13 110. The FDA concluded that “Overall, the studies support the proposed
14 indication and use. Definitely easy to remove in sheep.” Ex. A, Carr Decl. at ¶ 25.

15 **Admit.**

16 111. On July 23, 2003, BPV received a follow-up email with the FDA's amended
17 language regarding the required “clinical experience” section of the IFU. Ex. A, Carr
18 Decl. at ¶ 26.

19 **Admit.**

20 112. The FDA further directed BPV to “add a warning in the labeling about the
21 potential for recurrent pulmonary embolism if a device other than a Recovery Cone is
22 used” and provided recommended language. Ex. A, Carr Decl. at ¶ 26.

23 **Objection. Misstates evidence and incorrectly characterizes the FDA's action**
24 **as “directing” a specific action. The referenced exhibit/email invited Bard to let the**
25 **FDA know if there was a disagreement regarding the recommended language.**
26 **Subject to said objections, admit.**

1 113. Later that day, BPV accepted the FDA’s language and revised the
2 Recovery® Filter IFU to incorporate the FDA’s requirements. BPV sent the FDA a letter
3 with copies of its revised IFU. Ex. A, Carr Decl. at ¶ 26.

4 **Admit.**

5 114. On July 24, 2003, the FDA sent BPV a follow-up email directing BPV to
6 “format the Recovery Cone label such that the warnings and precautions appear before the
7 clinical experience section.” Ex. A, Carr Decl. at ¶ 27.

8 **Objection. Misstates evidence and incorrectly characterizes the FDA’s action**
9 **as “directing” a specific action. The referenced exhibit/email invited Bard to let the**
10 **FDA know if there was a disagreement regarding the recommended language.**
11 **Subject to said objections, admit.**

12 115. BPV complied and sent the FDA updated copies of its IFU. Ex. A, Carr
13 Decl. at ¶ 27.

14 **Objection. Misstates evidence and incorrectly suggests that BPV “complied”**
15 **with a “directive.” Subject to said objection, admit.**

16 116. On July 25, 2003, the FDA reviewer prepared her file summary and
17 recommendation after reviewing the *in-vitro*, *in-vivo* animal, and clinical testing, as well
18 as all other “items requested during pre-submission meetings” that were submitted with
19 the Recovery® 510(k) that “substantiate the temporary indication and removal of the”
20 filter. Ex. A, Carr Decl. at ¶ 28.

21 **Admit.**

22 117. The FDA reviewer recommended that “the device can be cleared for market
23 for retrieval, with the modified labeling submitted electronically on 7/23/03 (to be
24 submitted officially).” Ex. A, Carr Decl. at ¶ 28.

25 **Admit.**

26 118. On July 25, 2003, the FDA cleared the Recovery® Filter to be marketed for
27 retrievable indication, subject to the general controls and special controls of the FDCA,
28 after finding it substantially equivalent to the predicate device. Ex. A, Carr Decl. at ¶ 29.

1 **Admit the FDA cleared the Recovery filter to be marketed for optional filter**
2 **removal (BPV-17-01-00058124) and that the FDA indicated in the clearance letter on**
3 **July 25, 2003, that it distinguished between class II (special controls) devices and**
4 **class III (PMA) devices. See Bard SOF Ex. A at Ex. 23 (BPV-17-01-00058122).**

5 **C. Follow-Up Correspondence Regarding the “Dear Doctor Letter” and**
6 **IFU Changes for Recovery Filter for Percutaneous Retrieval (K031328)**

7 119. On September 17, 2004, BPV contacted the local FDA investigator in
8 Phoenix regarding BPV’s intent to send out a “Dear Doctor” letter (“DDL”) and to make
9 certain changes to the IFU for the Recovery® Filter. Ex. A, Carr Decl. at ¶ 30.

10 **Objection, statement contains inadmissible hearsay as to what the FDA is**
11 **reported to have said. Subject to that objection, admit that the document relied upon**
12 **states an intent to send a DDL. Deny the document relied upon states there was an**
13 **intent to make certain changes to the IFU re: the Recovery filter. Rather, the**
14 **referenced exhibit states: “We then discussed that we were sending the letter to re-**
15 **emphasize our IFU much like we had done with the small bead issue a few years**
16 **ago.” Bard SOF Ex. A at Ex. 24 (PBBPV-17-01-00097745- 46).**

17 120. BPV intended to revise the IFU to include warnings about fracture and
18 migration. Ex. A, Carr Decl. at ¶ 30.

19 **Objection, statement contains inadmissible hearsay as to what the FDA is**
20 **reported to have said. Subject to that objection, admit that the document relied upon**
21 **states “the letter would be addressing specific failure modes.” Bard SOF Ex. A at Ex.**
22 **24 (PBBPV-17-01-00097745-46). Deny it states BPV intended to revise the IFU to**
23 **include warnings about fracture and migration.**

24 121. The DDL was intended to inform doctors of BPV’s changes to the filter’s
25 IFU. Ex. A, Carr Decl. at ¶ 30.

26 **Admit that Mr. Carr states this was one of the goals of the DDL.**
27
28

1 122. Although the local FDA investigator did not determine whether the DDL
2 was necessary, BPV notified him as a “heads-up” regarding BPV’s plans. Ex. A, Carr
3 Decl. at ¶ 30.

4 **Objection, statement contains inadmissible hearsay as to what the FDA is**
5 **reported to have said. Additionally, misstates evidence. The document relied upon**
6 **states that the investigator did not make any determinations; the document states**
7 **“the local office is not responsible for determining” the issue when a DDL is**
8 **appropriate. Bard SOF Ex. A at Ex. 24 (PBBPV-17-01-00097745-46). Subject to said**
9 **objections, admit.**

10 123. On September 28, 2004, BPV and the FDA had a conversation regarding
11 BPV’s proposed DDL and the revised IFU. Ex. A, Carr Decl. at ¶ 31.

12 **Objection, statement contains inadmissible hearsay as to what the FDA is**
13 **reported to have said. Subject to said objection, admit that the document relied upon**
14 **so states.**

15 124. FDA stated that it was aware of the potential fracture and migration issues
16 associated with filters and was not particularly alarmed. Ex. A, Carr Decl. at ¶ 31.

17 **Objection, statement contains inadmissible hearsay as to what the FDA is**
18 **reported to have said. Subject to said objection, admit that the document relied upon**
19 **so states.**

20 125. FDA decided that “to be on the safe side,” BPV should send the DDL to the
21 agency. Ex. A, Carr Decl. at ¶ 31.

22 **Objection, statement contains inadmissible hearsay as to what the FDA is**
23 **reported to have said. Subject to said objection, admit that the document relied upon**
24 **so states.**

25 126. BPV and the FDA agreed that BPV should send the FDA a packet of
26 information, including the proposed DDL, a red-lined IFU, and an analysis of complaint
27 numbers, estimated rates, and literature rates regarding fracture and migration. Ex. A,
28 Carr Decl. at ¶ 31.

1 **Objection, statement contains inadmissible hearsay as to what the FDA is**
2 **reported to have said. Subject to said objection, admit that the document relied upon**
3 **so states.**

4 127. BPV would submit this information as a supplement to the Recovery® Filter
5 510(k) to enable the FDA to make a decision regarding whether BPV would need to file a
6 new 510(k). Ex. A, Carr Decl. at ¶ 31.

7 **Objection, statement contains inadmissible hearsay as to what the FDA is**
8 **reported to have said. Subject to said objection, admit that the document relied upon**
9 **so states.**

10 128. On October 5, 2004, BPV sent a letter to the FDA with the information
11 discussed in the September 28, 2004 meeting, including new proposed labeling, a red-
12 lined version of the previous IFU, a copy of its proposed DDL, and a chart of possible and
13 reported adverse events associated with the RNF. Ex. A, Carr Decl. at ¶ 32.

14 **Admit the document relied upon includes new proposed IFU language, a red-**
15 **lined version of the previous IFU, a copy of the proposed DDL and a chart of**
16 **possible and reported adverse events. Deny the chart only includes possible reported**
17 **adverse events, as it also contains information from a Society of Interventional**
18 **Radiology publication that was not requested by FDA when, based on the document**
19 **relied upon, the FDA requested Bard's threshold limits. Bard SOF Ex. A at Ex. 25**
20 **(BPV-17-01-00097732).**

21 129. BPV did not propose any changes to the design of the filter or delivery
22 system, and it emphasized that the proposed changes did not change the original intended
23 use, indications, or contraindications of the cleared Recovery® Filter. Ex. A, Carr Decl.
24 at ¶ 32.

25 **Admit.**

26 130. During this time period, Bard and the FDA actively discussed the safety and
27 efficacy of the Recovery Filter. Ex. A, Carr Decl. at ¶ 33.

1 **Objection, statement contains inadmissible hearsay as to what the FDA is**
2 **reported to have said. Also mischaracterizes the relied-upon document, which**
3 **demonstrates that the FDA could not make certain determinations from the**
4 **materials Bard submitted.**

5 131. Internal FDA emails describe members of FDA independently reviewing the
6 clinical performance of the Recovery® Filter. Ex. A, Carr Decl. at ¶ 33.

7 **Objection, statement contains inadmissible hearsay as to what the FDA is**
8 **reported to have said. Also mischaracterizes the relied-upon document, which**
9 **demonstrates that the FDA could not make certain determinations from the**
10 **materials Bard submitted.**

11 132. On Oct. 6, 2004, FDA personnel noted “detail analyses on the MDRs related
12 to Bard Recovery vena cava filter.” Ex. A, Carr Decl. at ¶ 33.

13 **Objection, statement contains inadmissible hearsay as to what the FDA is**
14 **reported to have said. Also mischaracterizes the relied-upon document, which**
15 **demonstrates that the FDA could not make certain determinations from the**
16 **materials Bard submitted.**

17 133. The FDA determined that Bard’s proposal to issue a “Dear Doctor Letter”
18 and to revise the IFU for the Recovery® Filter were appropriate. Ex. A, Carr Decl. at ¶
19 34.

20 **Objection, statement contains inadmissible hearsay as to what the FDA is**
21 **reported to have said. Subject to said objection, admit that the document relied upon**
22 **states the FDA indicated that it believe Bard’s proposed DDL was appropriate based**
23 **upon information provided to the FDA by Bard.**

24 134. On November 10, 2004, FDA noted that the FDA “agreed that Bard’s
25 proposal appears to be adequate.” Ex. A, Carr Decl. at ¶ 34.

26 **Objection, statement contains inadmissible hearsay as to what the FDA is**
27 **reported to have said. Subject to said objection, admit that the document relied upon**
28 **so states.**

1 135. On November 24, 2004, the FDA emailed BPV to notify it to expect an
2 official FDA response approving the proposed DDL and IFU changes and determining
3 that BPV would not need to file a new 510(k). Ex. A, Carr Decl. at ¶ 35.

4 **Admit.**

5 136. The FDA did require BPV to incorporate specific FDA revisions to the
6 proposed labeling and DDL. Ex. A, Carr Decl. at ¶ 35.

7 **Deny the FDA required BPV to act. The relied-upon document states any**
8 **revisions were called “suggested comments” by the FDA and described by Bard as**
9 **“suggested changes” from FDA, not requirements. Bard SOF Ex. A at Ex. 28 (BPV-**
10 **17-01-00029512-13).**

11 137. On November 28, 2004, BPV began revising its IFU and DDL to
12 incorporate the FDA-mandated changes, in order to send the DDL as soon as possible.
13 Ex. A, Carr Decl. at ¶ 36.

14 **Admit the relied upon document indicates Bard began to institute changes to**
15 **IFU and DDL on said date. Deny that said changes were “mandated.” The relied-**
16 **upon document states any revisions were “suggested comments” (Bard SOF Ex. A at**
17 **Ex. 28 (BPV-17-01-00029513)) and described by Bard as “suggested changes” from**
18 **FDA, not mandates. *Id.* at Ex. 29 (BPV-17-01-00102072-73).**

19 138. On November 30, 2004, BPV received the FDA’s formal letter determining
20 that the proposed changes were not significant under 21 CFR 807.81(a)(3), and that BPV
21 would not need to file a new 510(k). Ex. A, Carr Decl. at ¶ 37.

22 **Admit the underlying document indicates Bard received a letter from the FDA**
23 **on November 30, 2004. Deny the letter states the proposed changes were not**
24 **significant. The language in question reads: “it does not appear that you have**
25 **significantly changed or modified the design...” Bard SOF Ex. A at Ex. 30 (BPV-17-**
26 **01-00059079); *see also* 21 C.F.R. § 807.81(a)(3).**

1 139. The letter confirmed the FDA’s emailed instructions requiring BPV to
2 incorporate agency-specified language into BPV’s proposed DDL and revisions to the
3 IFU. Ex. A, Carr Decl. at ¶ 37.

4 **Admit the underlying document indicates Bard received a letter from the FDA**
5 **on November 30, 2004. Deny the letter provides agency-specific language. See Bard**
6 **SOF Ex. A at Ex. 30 (BPV-17-01-00059079). The language was described by Bard as**
7 **“suggested changes.” *Id.* at Ex. 29 (BPV-17-01-00102072-73).**

8 140. The FDA letter also stated that, if adverse event monitoring indicated
9 continuing improper use of the Recovery® Filter, the FDA may order additional
10 measures. Ex. A, Carr Decl. at ¶ 37.

11 **Deny. The relied-upon document states that if continued monitoring revealed**
12 **that measures fail to address improper use of the device, “additional measures may**
13 **be warranted in the future. It is your responsibility to determine if changes or**
14 **modifications to the device or its labeling could significantly affect the device’s safety**
15 **or effectiveness, and thus require submission of a new 510(k).” Bard SOF Ex. A at**
16 **Ex. 30 (BPV-17-01-00059079).**

17 141. BPV began distributing the DDL in December, 2004. Ex. A, Carr Decl. at ¶
18 38.

19 **Can neither admit nor deny. The underlying document does not contain a**
20 **distribution date. See Bard SOF Ex. A at Ex. 31.**

21 142. After a phone conversation with the FDA on January 10, 2005, BPV faxed
22 the FDA copies of its current IFU and as-mailed version of the DDL. Ex. A, Carr Decl. at
23 ¶ 38.

24 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
25 **admit that the document relied upon states: “Per our telephone conversation on**
26 **January 10, 2005.” Admit the date of the document is January 12, 2005.**

1 143. On January 21, 2005, the FDA and BPV had a telephone conference to
2 discuss the revised IFU and as-mailed DDL, with BPV assuring the FDA that both were
3 being distributed. Ex. A, Carr Decl. at ¶ 39.

4 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
5 **admit that the document relied upon so states. Admit the date of the document is**
6 **January 21, 2005.**

7 144. BPV also sought FDA prior review of another planned update, a BPV Dear
8 Colleague Letter (“DCL”) to customers concerning the Recovery® Filter’s performance
9 in bariatric patients. Ex. A, Carr Decl. at ¶ 39.

10 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
11 **admit the document relied upon so states.**

12 145. BPV and the FDA also discussed BPV’s plan to create a clinical registry to
13 further evaluate the safety and effectiveness of the Recovery® filter in patients, as well as
14 a formal survey of current Recovery® Filter users, and a formal survey of specialists
15 treating bariatric patients. Ex. A, Carr Decl. at ¶ 39.

16 **Objection, statement contains inadmissible hearsay as to what the FDA is**
17 **reported to have said. Subject to said objection, admit that the document relied upon**
18 **contains this information. Bard has presented no evidence a clinical registry was**
19 **created.**

20 146. The FDA reiterated that it was “very pleased with the scientific approach
21 [BPV was] taking to better understand the risk/benefit of the Recovery Filter in bariatric
22 patients,” and was “very interested in hearing about the outcomes of [BPV’s] planned
23 surveys, expert panel meeting, and clinical registry.” Ex. A, Carr Decl. at ¶ 39.

24 **Objection, statement contains inadmissible hearsay as to what the FDA is**
25 **reported to have said. Subject to said objection, admit that the document relied upon**
26 **so states.**

1 147. In response to BPV's inquiry, the FDA indicated it had no concerns with
2 BPV's approach, and appreciated that BPV was being proactive in its communications
3 with both the FDA and its customers. Ex. A, Carr Decl. at ¶ 39.

4 **Objection, statement contains inadmissible hearsay as to what the FDA is**
5 **reported to have said. Subject to said objection, admit that the document relied upon**
6 **so states.**

7 148. The day after the telephone conference, BPV emailed the FDA, per the
8 FDA's request: (1) a draft of the proposed DCL, (2) a formal survey of current
9 Recovery® Filter users, and (3) a formal survey of specialists treating bariatric patients.
10 Ex. A, Carr Decl. at ¶ 40.

11 **Admit Bard emailed FDA on January 22, 2005.**

12 149. On January 27, 2005, BPV contacted the FDA's local investigator in
13 Phoenix to communicate the same information. Ex. A, Carr Decl. at ¶ 41.

14 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
15 **admit that the document relied upon so states.**

16 150. The contact report quotes the FDA investigator as saying, "I am so
17 impressed with the ethical approach BPV is taking with this product." Ex. A, Carr Decl.
18 at ¶ 41.

19 **Objection, statement c inadmissible hearsay as to what the FDA investigator is**
20 **reported to have said. Subject to said objection, admit that the document relied upon**
21 **contains this quote.**

22 151. On February 4, 2005, BPV contacted the FDA again to discuss the DCL.
23 Ex. A, Carr Decl. at ¶ 42.

24 **Admit.**

25 152. The DCL was intended to inform customers of BPV's internal analysis of
26 reported adverse events related to the Recovery® Filter, particularly those events
27 associated with bariatric patients. Ex. A, Carr Decl. at ¶ 42.
28

1 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
2 **admit that the document relied upon so states. Deny that the DCL fully disclosed**
3 **information Bard was aware of at the time it issued the DCL.**

4 153. On February 8, 2005, the FDA sent a letter to BPV requesting information
5 so the FDA could evaluate medical device reports that had been reported to the FDA. Ex.
6 A, Carr Decl. at ¶ 43.

7 **Admit.**

8 154. BPV followed up with a telephone conference. Ex. A, Carr Decl. at ¶ 43.

9 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
10 **admit that the document relied upon indicates a phone conversation on February 8,**
11 **2005.**

12 155. BPV further discussed the DCL letter with the FDA. Ex. A, Carr Decl. at
13 ¶ 43.

14 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
15 **admit that the document relied upon states these items amongst others were**
16 **discussed.**

17 156. The FDA advised that “it is a very good idea to send this type of letter and
18 [the agency] appreciates the BPV being so proactive.” Ex. A, Carr Decl. at ¶ 43.

19 **Objection, statement contains inadmissible hearsay as to what the FDA is**
20 **reported to have said. Subject to said objection, admit that the document relied upon**
21 **is correctly quoted.**

22 157. Also on February 8, 2005, BPV faxed the FDA responses to FDA questions
23 regarding the dissemination of the DDL. Ex. A, Carr Decl. at ¶ 43.

24 **Admit.**

25 158. BPV and the FDA had another telephone conference on February 14, 2005.
26 Ex. A, Carr Decl. at ¶ 44.

1 **Objection, statement contains inadmissible. Subject to said objection, admit**
2 **the relied-upon document indicates a phone conversation occurred on February 14,**
3 **2005.**

4 159. The conference discussed: (1) the recent bariatric surgeons panel meeting in
5 New Orleans, (2) whether BPV was planning further device modifications, and (3) the
6 FDA's February 8, 2005 request for information. Ex. A, Carr Decl. at ¶ 44.

7 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
8 **admit that the document relied upon states that these items were discussed.**

9 160. The FDA stated that it required additional information regarding the total
10 number of Recovery Filters sold in the U.S. to identify trends of adverse events
11 experienced by retrievable filters generally. Ex. A, Carr Decl. at ¶ 44.

12 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
13 **admit that the document relied upon states that these items were discussed.**

14 161. The FDA specified the format for submitting this information. Ex. A, Carr
15 Decl. at ¶ 44.

16 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
17 **admit that the document relied upon states that these items were discussed.**

18 162. On February 28, 2005, BPV responded by letter to the FDA's February 8,
19 2005 requests and provided the additional information required by the FDA. Ex. A, Carr
20 Decl. at ¶ 45.

21 **Admit that BPV provided additional information. Deny that this information**
22 **was "required."**

23 163. BPV sent the FDA an update to its October 5, 2004 chart regarding possible
24 and reported adverse events associated with the Recovery® Filter and copies of the filter's
25 labeling and marketing materials. Ex. A, Carr Decl. at ¶ 45.

26 **Admit.**

27 164. On February 28, 2005, BPV and the FDA had a telephone conference. Ex.
28 A, Carr Decl. at ¶ 46.

1 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
2 **admit that the document relied upon indicates a phone conversation occurred on**
3 **February 28, 2005.**

4 165. They discussed the DCL, the New Orleans panel meeting, and the two
5 surveys. Ex. A, Carr Decl. at ¶ 46.

6 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
7 **admit that the document relied upon states that these items were discussed.**

8 166. The FDA required BPV to forward for agency review: (1) the final draft of
9 the DCL, (2) a summary of the panel meeting, and (3) summaries of the two surveys. Ex.
10 A, Carr Decl. at ¶ 46.

11 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
12 **admit that the document relied upon states that these items were discussed. Also**
13 **deny that the FDA “required” any particular item.**

14 167. BPV and the FDA also discussed BPV’s plan to make additional
15 modifications via a Special 510(k) and arranged a meeting on March 21 to review BPV’s
16 data for the Special 510(k). Ex. A, Carr Decl. at ¶ 46.

17 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
18 **admit that the document relied upon states that these items were discussed.**

19 168. The FDA thanked BPV “for being so forthright with information” and “said
20 the other removable filter manufacturers have been less than cooperative in sharing
21 information.” Ex. A, Carr Decl. at ¶ 46.

22 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
23 **admit that the document relied upon is correctly quoted.**

24 169. BPV assured FDA that BPV “would continue to cooperate, as Bard is
25 deeply committed to patient safety and to obtaining a better understanding of the
26 risk/benefit of the Recovery filter in morbidly obese patients.” Ex. A, Carr Decl. at ¶ 46.

27 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
28 **admit that the document relied upon is correctly quoted.**

1 **IV. G2® Filter System:**

2 **A. G2® Filter System (K050558)**

3 170. On March 2, 2005, BPV submitted a Special 510(k) application for a
4 modified Recovery® Filter (to be called the G2® Filter). Ex. A, Carr Decl. at ¶ 47.

5 **Admit.**

6 171. The application, made significant dimensional modifications to the predicate
7 device, the Recovery® Filter, but incorporated no material changes or additional
8 components. Ex. A, Carr Decl. at ¶ 47.

9 **Admit.**

10 172. Included in the 510(k) submission were results from acute in vivo animal
11 testing BPV conducted to evaluate the modified delivery system. Ex. A, Carr Decl. at ¶
12 47.

13 **Admit.**

14 173. Also included were results from 21 *in-vitro* bench tests BPV conducted on
15 the modified Recovery® Filter, those being Dimensional Testing, Filter Migration
16 Resistance, Filter Radial Strength, Filter Respiratory Fatigue Resistance, Filter
17 Diaphragmatic Fatigue Resistance, Filter Centering, Filter Removal Force, Sheath and
18 Introducer Kink Resistance, Dilator Removal, Dilator Hub Strength, Dilator to Hub Joint,
19 Marker Band Security, Pusher Rod Kink Resistance, Spline and Pusher Wire Joint Tensile
20 Strength, Filter Deployment Accuracy, Deployment Force, Filter Advancement, Deployed
21 Filter Configuration, Filter Centering, Filter Hook and Spline Interaction, Number of
22 Exposures, and Warehouse Environment, and Truck/Air Transport. Ex. A, Carr Decl. at ¶
23 47.

24 **Admit.**

25 174. BPV performed all testing in conformance with the FDA guidance
26 document: “Guidance for Cardiovascular Intravascular Filter 510(k) Submission.” Ex. A,
27 Carr Decl. at ¶ 47.
28

1 **Deny to the extent it is suggested that the Guidance document required**
2 **specific testing or protocols. See Ex. 5 at 51:15-17.**

3 175. BPV conducted a risk analysis, a Risk Assessment and Design Failure
4 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO
5 14971:2000, Medical Devices – Application of risk management to medical devices and
6 BS EN 1441:1998, Medical Devices-Risk Analysis, to assure that risks posed by the
7 design were acceptable. Ex. A, Carr Decl. at ¶ 47.

8 **Admit the document relied upon so states.**

9 176. This analysis did not identify any safety or effectiveness issues. Ex. A, Carr
10 Decl. at ¶ 47.

11 **Admit the document relied upon so states.**

12 177. The design verification and validation were performed in conformance with
13 FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular
14 Filter 510(k) Submission”; BS EN 12006-3:1999 entitled, “Non-Active Surgical Implants
15 – Particular Requirements for Cardiac and Vascular Implants – Part 3: Endovascular
16 Devices”; FDA guidance document, Design Control Guidance for Medical Device
17 Manufacturers, dated March 11, 1997; and the design control requirements under 21 CFR
18 § 820.30. Ex. A, Carr Decl. at ¶ 47.

19 **Admit the document relied upon so states. Deny to the extent it is suggested**
20 **that the Guidance document required specific testing or protocols. See Ex. 5 at**
21 **51:15-17. Also deny to the extent that 21 C.F.R. § 820.30 does not contain specific**
22 **design controls for any IVC filters. See id.; Excerpts from Deposition Transcript of**
23 **David Kessler (July 31, 2017), hereinafter Exhibit 11, at 108-109.**

24 178. The submission also included proposed labeling for the modified
25 Recovery® Filter in conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 47.

26 **Admit the document relied upon contains proposed IFU language. Deny to the**
27 **extent that 21 C.F.R. § 807.87(e) does not contain specific labeling language for IVC**
28 **filters.**

1 179. The submission also included a summary of safety and effectiveness
2 information upon which a substantial equivalence determination could be based, as
3 required by the Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr
4 Decl. at ¶ 47.

5 **Admit.**

6 180. On March 24, 2005, BPV and the FDA met to discuss FDA questions
7 regarding BPV's Special 510(k) submission, the bariatric surgeon panel meeting, and the
8 proposed DCL. Ex. A, Carr Decl. at ¶ 48.

9 **Admit.**

10 181. The FDA had no comments on BPV's DCL – "it looks good, but since this
11 is not an official [i.e. regulated] action the content is up to you and we don't give
12 approval/disapproval. We appreciate you sharing it with us, though." Ex. A, Carr Decl.
13 at ¶ 48.

14 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
15 **admit that the document relied upon is correctly quoted.**

16 182. The FDA warned that it might require a pre-market proof of concept 50
17 patient study before clearing the new device, but would evaluate the sufficiency of the
18 information BPV had provided. Ex. A, Carr Decl. at ¶ 48.

19 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
20 **admit that the document relied upon attributes this statement to FDA.**

21 183. An FDA internal memorandum circulated on March 29, 2005 reviewed
22 BPV's Special 510(k) and concluded, "While these changes may have resulted in less of a
23 chance of migration of the device, they may have resulted in more problems with retrieval
24 of the device, especially after the healing process takes place. An unlimited time to
25 retrieval may no longer be appropriate." Ex. A, Carr Decl. at ¶ 49.

26 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
27 **admit that the document relied upon is correctly quoted.**

28

1 184. The FDA reviewer recommended that FDA require BPV to “conduct a
2 small ‘proof of concept’ study to determine if there should be a maximum implant period,
3 or if the current label with no such limitation is still appropriate.” Ex. A, Carr Decl. at
4 ¶ 49.

5 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
6 **admit that the document relied upon is correctly quoted. Deny the document**
7 **indicates a requirement set by FDA as to any study; the “Recommendation” section**
8 **contains the quote.**

9 185. On March 30, 2005, the FDA responded to BPV’s Special 510(k) by
10 requiring additional information. Ex. A, Carr Decl. at ¶ 50.

11 **Admit.**

12 186. The FDA prohibited BPV from marketing the device until it had provided
13 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 50.

14 **Admit.**

15 187. If BPV failed to respond within 30 days, the FDA would have treated this
16 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 50.

17 **Admit.**

18 188. The FDA required the small pre-market “proof of concept” clinical study
19 previously described to assess whether the current label for retrieval indication was still
20 appropriate (Question 2). Ex. A, Carr Decl. at ¶ 50.

21 **Deny. The FDA could not correlate the information previously submitted by**
22 **Bard. It therefore “recommended” a “proof of concept” study. Bard SOF Ex. A at**
23 **Ex. 46 (BPV-17-01-00125312).**

24 189. The FDA directed BPV to provide the histology assessment and
25 representative slides from BPV’s animal study conducted in conjunction with this
26 submission, and comparative slides from the animal study of the predicate Recovery®
27 Filter (Question 1). Ex. A, Carr Decl. at ¶ 50.

Objection, statement contains inadmissible hearsay. Subject to said objection, admit that the document relied upon indicates a request by the FDA to BPV to provide the referenced information.

190. The FDA further requested BPV to add a boxed warning to the modified Recovery® Filter labeling with specified language regarding use in obese patients, and a warning that central venous lines may cause displacement or fracture (Question 3). Ex. A, Carr Decl. at ¶ 50.

Objection, statement contains inadmissible hearsay. Subject to said objection, admit that the document relied upon indicates a request by the FDA to BPV to provide the referenced information.

191. Specifically, FDA requested BPV to add a boxed warning at the beginning of the “Warnings” section that stated: “Warning: The safety and effectiveness of the Recovery Filter System in morbidly obese patients has not been established. There have been fatal device adverse events reported in this population.” Ex. A, Carr Decl. at ¶ 50.

Objection, statement contains inadmissible hearsay. Subject to said objection, admit that the document relied upon indicates a request by the FDA to BPV to provide the referenced information.

192. On April 19, 2005, BPV emailed FDA its informal draft responses to FDA’s demand for additional information. Ex. A, Carr Decl. at ¶ 51.

Admit that a draft response was sent. Plaintiffs are unable to verify whether the document was emailed to the FDA.

193. In response to FDA’s request for certain data (Question 1), BPV provided the pathology reports from the animal study for the predicate device as well as pathology reports and clinical evaluation for the subject device. Ex. A, Carr Decl. at ¶ 51.

Admit.

194. In response to FDA’s demand for clinical data (Question 2), BPV provided a detailed justification for why in vivo animal testing was sufficient to demonstrate the safety and effectiveness of long-term retrievability of the G2 Filter, as the “animal studies

1 are highly predictive of the [G2] Filter's performance in humans, specifically concerning
2 long-term retrieval." Ex. A, Carr Decl. at ¶ 51.

3 **Admit that Bard provided an explanation of why it felt in vivo animal testing**
4 **was sufficient to demonstrate safety and effectiveness of long-term retrievability of**
5 **the G2 Filter. Deny that such testing was sufficient to make such demonstration.**

6 195. BPV discussed the extensive *in-vivo* animal and human clinical studies
7 conducted on the predicate device (the Recovery Filter) evaluating long-term
8 retrievability, and compared it to the in vivo animal testing conducted on the subject G2
9 Filter, to support that the in vivo testing would be predictive of clinical experience. Ex. A,
10 Carr Decl. at ¶ 51.

11 **Admit that BPV discussed in-vivo clinical studies. Deny that such studies**
12 **were "extensive" or adequate.**

13 196. In response to FDA's request for a boxed warning that stated "The safety
14 and effectiveness of the Recovery Filter System in morbidly obese patients has not been
15 established" (Question 3), BPV responded that "The Indications for Use of all
16 commercially available inferior vena cava (IVC) filters, including the Recovery Filter, do
17 not specifically address the safety and effectiveness of the device in any one patient
18 population." Ex. A, Carr Decl. at ¶ 51.

19 **Admit.**

20 197. In response to FDA's request for a boxed warning in the "Warnings" section
21 that stated "There have been fatal device-related adverse events reported in this [morbidly
22 obese] population" (Question 3), BPV proposed to add the following alternative statement
23 to the "Potential Complications" section of the labeling with the following similar
24 language: "There have been reports of complications, including death, associated with the
25 use of the Recovery Filter System in morbidly obese patients." Ex. A, Carr Decl. at ¶ 51.

26 **Admit.**

27 198. BPV further responded that "Currently, there is a statement in the Recovery
28 Filter IFU linking all of the potential complications to death. BPV continues to analyze

1 available published literature on IVC filters and is conducting formal research to better
2 understand the morbidly obese patient population. Physicians have indicated that there is
3 a significant need to allow an IVC Filter to remain in place for an extended period of time
4 (> 30 days) in certain high risk patient populations, including morbidly obese patients.”

5 Ex. A, Carr Decl. at ¶ 51.

6 **Admit.**

7 199. BPV attached the proposed labeling to the email for FDA’s review. Ex. A,
8 Carr Decl. at ¶ 51.

9 **Unable to admit or deny. The document relied upon does not show an**
10 **attachment.**

11 200. In response to FDA’s request for a warning that central venous lines may
12 cause the filters to move or fracture, BPV stated “there is no bench-top testing or clinical
13 evidence that shows that the Recovery Filter is susceptible to fracture or movement due to
14 the use of central venous lines.” Ex. A, Carr Decl. at ¶ 51.

15 **Admit.**

16 201. “Additionally, there are no inherent design characteristics that would make
17 the Recovery Filter likely to entrap the central venous lines, potentially leading to
18 movement or fracture. There have been no reported complaints of guidewire and/or
19 central venous line entrapment associated with the Recovery Filter.” Ex. A, Carr Decl. at
20 ¶ 51.

21 **Admit that Bard made this statement. Deny that evidence has been presented**
22 **as to the veracity of this statement.**

23 202. On April 27, 2005, BPV sent a letter to the FDA requesting a 30 day
24 extension to formally respond to the FDA’s questions of March 30, 2005. Ex. A, Carr
25 Decl. at ¶ 52.

26 **Admit.**

27 203. The FDA granted BPV’s request on April 28, 2005. Ex. A, Carr Decl. at ¶
28 52.

1 **Admit.**

2 204. On May 2, 2005, FDA circulated an internal memorandum reviewing the in
3 vivo animal testing and detailing that if a proof of concept human clinical study would be
4 required, the clinical protocol should incorporate certain considerations in study design.
5 Ex. A, Carr Decl. at ¶ 53.

6 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
7 **admit that the document relied upon indicates that the “sponsor should be**
8 **encouraged” to develop certain data and consider certain items in its methodology.**
9 **Bard SOF Ex. A at Ex. 50 (FDA_PRODUCTION_00000190).**

10 205. On May 6, 2005, the FDA and BPV had a conference during which the FDA
11 again expressed its view that BPV was required to provide pre-market clinical data to
12 determine whether the device modifications might affect its long-term retrievability. Ex.
13 A, Carr Decl. at ¶ 54.

14 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
15 **admit that the document relied upon indicates the FDA “requested” a pre-market**
16 **study.**

17 206. The FDA would not approve BPV’s proposed changes without this clinical
18 data. Ex. A, Carr Decl. at ¶ 54.

19 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
20 **deny. Bard SOF Ex. A at Ex. 51 does not indicate that clinical data was an**
21 **indispensable requirement for clearance. Admit that the document suggests that**
22 **BPV did not provide sufficient data for the FDA to determine whether the proposed**
23 **changes might affect the filter’s long-term retrievability, and that substantial**
24 **equivalence could not be evaluated without pre-market clinical data. *Id.* at Ex. 51**
25 **(BPV-17-01-00125423).**

26 207. The FDA required evidence that dimensional modifications to improve
27 migration and fracture resistance would not adversely affect the long-term retrievability of
28 the device. Ex. A, Carr Decl. at ¶ 54.

1 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
2 **deny. The document suggests that the FDA could not make substantial equivalence**
3 **determination without the requested information. Bard SOF Ex. A at Ex. 51 (BPV-**
4 **17-01-00125423). Deny that the FDA “required” evidence that dimensional**
5 **modifications to improve migration and fracture resistance would not adversely**
6 **affect the long-term retrievability of the device; the relied upon document states that**
7 **“the FDA did not have enough data in the initial Special 510(k) to determine**
8 **whether the changes might affect its long-term retrievability.” *Id.***

9 208. In response to FDA’s request for clinical data, BPV was prepared to submit
10 an Investigational Device Exemption (“IDE”) clinical trial proposal to conduct the study
11 sought by the FDA. Ex. A, Carr Decl. at ¶ 54.

12 **Admit the relied-upon document indicates was prepared to submit an**
13 **Investigational Device Exemption (“IDE”) clinical trial proposal to conduct the**
14 **study sought by the FDA.**

15 209. However, BPV still hoped to gain clearance of its Special 510(k) for a more
16 limited indication, an acute retrieval period of 3 to 4 weeks. Ex. A, Carr Decl. at ¶ 54.

17 **Admit the relied-upon document indicates it was prepared to submit an**
18 **Investigational Device Exemption (“IDE”) clinical trial proposal to conduct the**
19 **study requested by the FDA.**

20 210. On May 20-21, 2005, BPV began distributing the DCL. Ex. A, Carr Decl.
21 at ¶ 55.

22 **Admit.**

23 211. On May 27, 2005, the FDA and BPV had another telephone conference.
24 Ex. A, Carr Decl. at ¶ 56.

25 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
26 **admit that the document relied indicates FDA contact on May 27, 2005.**

27 212. FDA informed BPV that it would not clear an indication for acute retrieval
28 of 3 to 4 weeks without clinical data. Ex. A, Carr Decl. at ¶ 56.

1 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
2 **admit that the document relied upon attributes this statement to the FDA.**

3 213. The FDA determined that “all new and modified retrievable filters will
4 require clinical data to support a 510(k) determination of substantial equivalence.” Ex. A,
5 Carr Decl. at ¶ 56.

6 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
7 **admit that the document relied upon attributes this statement to the FDA.**

8 214. The FDA stated that the most BPV could obtain from its Special 510(k) for
9 the modified Recovery® Filter would be a “substantial equivalence with limitations”
10 determination identical to the original Recovery Filter system’s initial clearance as a
11 permanent filter. Ex. A, Carr Decl. at ¶ 56.

12 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
13 **admit that the document relied upon attributes this statement to the FDA.**

14 215. “The limitations would require BPV to include a statement in the IFU
15 indicating that the safety and effectiveness of the filter as a retrievable filter has not been
16 established.” Ex. A, Carr Decl. at ¶ 56.

17 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
18 **admit that the document relied upon attributes this statement to the FDA.**

19 216. On June 3, 2005, BPV formally responded to FDA’s demand for additional
20 information dated March 30, 2005, after conferring on multiple occasions with FDA about
21 those demands. Ex. A, Carr Decl. at ¶ 57.

22 **Admit.**

23 217. BPV requested FDA to convert its Special 510(k) submission into a
24 traditional 510(k) that sought clearance of the modified Recovery® Filter solely for
25 permanent use. Ex. A, Carr Decl. at ¶ 57.

26 **Admit.**

27 218. BPV’s traditional 510(k) was essentially identical to the Special 510(k)
28 submission with minor exceptions. Ex. A, Carr Decl. at ¶ 57.

1 **Admit document relied upon states the information presented is essentially**
2 **identical. Deny characterization that the exceptions were “minor.”**

3 219. The converted 510(k) made changes to the labeling and IFU to include the
4 BPV’s proposed alternative statement to FDA’s request for a boxed warning concerning
5 reports of complications, including death, associated with the Recovery Filter in morbidly
6 obese patients, as well as the changes concerning the limitations language required by the
7 FDA during the May 27, 2005 telephone conference. Ex. A, Carr Decl. at ¶ 57.

8 **Admit.**

9 220. The 510(k) also provided protocols and reports for design
10 verification/validation and *in-vivo* non clinical testing. Ex. A, Carr Decl. at ¶ 57.

11 **Admit.**

12 221. On July 26, 2005, FDA circulated an internal memorandum reviewing
13 BPV’s draft informal responses dated April 19, 2005 to FDA’s demand for additional
14 information on March 30, 2005. Ex. A, Carr Decl. at ¶ 58.

15 **Admit.**

16 222. After reviewing BPV’s response to FDA’s demand for certain in vivo data
17 (Question 1), the FDA reviewer recommended that FDA require BPV to provide
18 additional data or scientific rationale for why the *in-vivo* animal data is applicable to the
19 subject device when indicated for permanent placement. Ex. A, Carr Decl. at ¶ 58.

20 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
21 **admit that the document relied upon attributes this statement to the FDA.**

22 223. After reviewing BPV’s response to FDA’s demand for clinical data
23 (Question 2), the FDA reviewer stated that “Given that [BPV] is pursuing clearance of the
24 subject device with an indication for permanent placement, this deficiency is no longer
25 applicable.” Ex. A, Carr Decl. at ¶ 58.

26 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
27 **admit that the document relied upon attributes this statement to the FDA.**

1 224. “Historically, clinical data has not always been required for a clearance of a
2 modified device with an indication for permanent placement if FDA believes that the
3 device modifications can be adequately assess through *in vitro* and in vivo testing.” Ex.
4 A, Carr Decl. at ¶ 58.

5 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
6 **admit that the document relied upon attributes this statement to the FDA.**

7 225. BPV’s “bench testing demonstrates that the device performs as good as or
8 better than the predicate device; however, [BPV] has not provided data which
9 demonstrates that the device modifications will not cause adverse reactions to the tissue
10 when the device is permanently implanted in the IVC.” Ex. A, Carr Decl. at ¶ 58.

11 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
12 **admit that the document relied upon attributes this statement to the FDA.**

13 226. BPV “should provide in vivo data which demonstrates that the proposed
14 device modifications do not adversely affect the tissue of the IVC.” Ex. A, Carr Decl. at ¶
15 58.

16 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
17 **admit that the document relied upon attributes this statement to the FDA.**

18 227. After reviewing BPV’s response to FDA’s request for a boxed warning for
19 morbidly obese patients (Question 3), the FDA reviewer stated that BPV’s justification for
20 not including a limitation statement regarding safety and effectiveness in morbidly obese
21 patients, and BPV’s proposed alternative labeling language in the “Potential
22 Complications” section instead of the “Warnings” section, was “acceptable as it
23 adequately captures the information known to date regarding the implantation of the
24 Recovery Filter System in morbidly obese patients.” Ex. A, Carr Decl. at ¶ 58.

25 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
26 **admit that the document relied upon attributes this statement to the FDA.**

27 228. In response to BPV’s response to FDA’s demand for a warning for central
28 venous lines causing filter migration or fracture (Question 3), the FDA reviewer discussed

1 BPV's response with FDA colleagues "to determine what information FDA would like to
2 see in the labeling. At this time, it is unclear what evidence led FDA to request the
3 proposed language." Ex. A, Carr Decl. at ¶ 58.

4 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
5 **admit that the document relied upon attributes this statement to the FDA.**

6 229. Therefore, FDA found BPV's response "acceptable." Ex. A, Carr Decl. at
7 ¶ 58.

8 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
9 **admit that the document relied upon attributes this statement to the FDA.**

10 230. The FDA reviewer "thoroughly reviewed" BPV's labeling but found that
11 "while the labeling has been modified appropriately to reflect the use of the subject device
12 as a permanent filter, the name of the device still implie[d] that it may be used off-label as
13 a retrievable filter. This is especially true given that the currently marketed Recovery
14 Filter System is indicated for device retrieval." Ex. A, Carr Decl. at ¶ 58.

15 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
16 **admit that the document relied upon attributes this statement to the FDA.**

17 231. The FDA reviewer recommended that FDA require BPV to change the
18 device name so that retrievability is not implied by the name. BPV should be further
19 required to "remove all references to the device as the Recovery Filter System in the
20 Instructions for Use, Indications for Use, 510(k) Summary and Package Labeling." Ex. A,
21 Carr Decl. at ¶ 58.

22 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
23 **admit that the document relied upon attributes this statement to the FDA. Deny that**
24 **specific language was required. The changes were "requested." Bard SOF Ex. A at**
25 **Ex. 55 (FDA_PRODUCTION_00000182).**

26 232. On July 26, 2005, BPV and the FDA discussed BPV's submission for the
27 modified Recovery® Filter (G2®) for permanent indication. Ex. A, Carr Decl. at ¶ 59.

28 **Admit.**

1 233. The FDA sought histopathology data from BPV's animal study, and BPV
2 explained the data it had collected. Ex. A, Carr Decl. at ¶ 59.

3 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
4 **admit that the document relied upon attributes this statement to the FDA.**

5 234. On July 27, 2005, the FDA emailed a request for an electronic version of
6 BPV's 510(k) submission. Ex. A, Carr Decl. at ¶ 60.

7 **Admit.**

8 235. BPV provided an electronic version, and stated that it would include
9 electronic versions of all future submissions. Ex. A, Carr Decl. at ¶ 60.

10 **Admit.**

11 236. On July 28, 2005, the FDA officially responded to BPV's traditional 510(k)
12 submission for the modified Recovery® Filter and demanded additional information. Ex.
13 A, Carr Decl. at ¶ 61.

14 **Admit.**

15 237. The FDA prohibited BPV from marketing the device until it had provided
16 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 61.

17 **Admit.**

18 238. If BPV failed to respond within 30 days, the FDA would have treated this
19 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 61.

20 **Admit.**

21 239. The FDA questioned how the animal data included in the submission
22 "provides an assurance of safety and effectiveness of the modified Recovery Filter as a
23 permanent implant," and required BPV to provide additional in vivo data or a scientific
24 rationale for why the animal data is applicable to the permanent placement indication
25 (Question 1). Ex. A, Carr Decl. at ¶ 61.

26 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
27 **admit that the document relied upon attributes this statement to the FDA. Admit**
28

1 **that additional information was requested. Deny that specific information was**
2 **“required.” Bard SOF Ex. A at Ex. 58 (BPV-17-01-00125220).**

3 240. The FDA also required BPV to change the name of the modified Recovery®
4 Filter to reflect its permanent indication, because “Recovery” implied that it may be used
5 off-label as a retrievable filter (Question 2). Ex. A, Carr Decl. at ¶ 61.

6 **Deny that this was a “requirement.” The FDA indicated that such changes**
7 **should be made. Bard SOF Ex. A at Ex. 58 (BPV-17-01-00125220).**

8 241. On the same day, BPV and the FDA had a telephone conversation to discuss
9 the FDA’s required additional information. Ex. A, Carr Decl. at ¶ 62.

10 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
11 **admit that the document relied upon states that a telephone call occurred on this**
12 **date.**

13 242. The FDA reaffirmed its requirement that BPV change the trade name of the
14 Recovery® Filter to reflect the limited clearance BPV sought solely for permanent
15 indication use. Ex. A, Carr Decl. at ¶ 62.

16 **Objection, statement contains inadmissible hearsay. Subject to said objection,**
17 **admit that the document relied upon attributes this request to the FDA.**

18 243. Eventually, BPV changed the name of the filter to G2®. Ex. A, Carr Decl.
19 at ¶ 62.

20 **Admit.**

21 244. On August 10, 2005, BPV provided the additional information that the FDA
22 required on July 28, 2005. Ex. A, Carr Decl. at ¶ 63.

23 **Admit that Bard provided additional information to the FDA. Deny that the**
24 **FDA “required” this information.**

25 245. In response to FDA’s demand (Question 1), BPV provided its scientific
26 rationale for how the objectives of the *in-vivo* animal study relate to the permanent filter
27 indication. Ex. A, Carr Decl. at ¶ 63.

1 **Objection. The use of the word “demand” is misleading. Subject to said**
2 **objection, admit.**

3 246. In response to FDA’s demand (Question 2), BPV confirmed that the name
4 of the Recovery Filter would be changed to G2, including in the Indications for Use,
5 Instructions for Use, 510(k) Summary, and Package Labeling, which was provided for
6 FDA review. Ex. A, Carr Decl. at ¶ 63.

7 **Objection. The use of the word “demand” is misleading. Subject to said**
8 **objection, admit.**

9 247. On August 19, 2005, responding to another information demand from the
10 FDA, BPV emailed the FDA a revised copy of its 510(k) summary. Ex. A, Carr Decl. at ¶
11 64.

12 **Objection. The use of the word “demand” is misleading. Subject to said**
13 **objection, admit.**

14 248. On August 22, 2005, responding to another information demand from the
15 FDA, BPV sent the FDA a revised copy of the G2® IFU, which included the alternate
16 statement concerning use of the Recovery® Filter in morbidly obese patients, and
17 replaced “Recovery” with the new trade name “G2.” Ex. A, Carr Decl. at ¶ 65.

18 **Objection. The use of the word “demand” is misleading. Subject to said**
19 **objection, admit.**

20 249. On August 23, 2005, FDA internally circulated a memorandum reviewing
21 BPV’s responses to FDA’s demand for additional information on July 28, 2005. Ex. A,
22 Carr Decl. at ¶ 66.

23 **Objection. The use of the word “demand” is misleading. Subject to said**
24 **objection, admit.**

25 250. After reviewing BPV’s response to FDA’s demand for additional in vivo
26 data (Question 1), the FDA reviewer stated that “BPV submitted an appropriate rationale
27 for why the study conducted and previously reviewed by FDA is applicable to the filter
28 when indicated for permanent placement.” Ex. A, Carr Decl. at ¶ 66.

1 **Objection. The use of the word “demand” is misleading. Furthermore,**
2 **statement contains inadmissible hearsay. Subject to said objections, admit that the**
3 **document relied upon attributes this statement to the FDA reviewer.**

4 251. The FDA reviewer discussed BPV’s rationale with FDA colleagues who
5 corroborated that the data collected was applicable to the filter when indicated for
6 permanent placement. FDA had no further questions on that subject. Ex. A, Carr Decl. at
7 ¶ 66.

8 **Objection. The use of the word “demand” is misleading. Furthermore,**
9 **statement contains inadmissible hearsay. Subject to said objections, admit that the**
10 **document relied upon attributes this statement to the FDA reviewer.**

11 252. After reviewing BPV’s response to FDA’s demand to change the trade name
12 and remove all references to that name (Question 2), the FDA reviewer noted that BPV
13 changed the name of the filter to the G2 Filter and removed all references to the former
14 device name. Ex. A, Carr Decl. at ¶ 66.

15 **Objection. The use of the word “demand” is misleading. Furthermore,**
16 **statement contains inadmissible hearsay. Subject to said objections, admit that the**
17 **document relied upon attributes this statement to the FDA reviewer.**

18 253. The FDA reviewer required BPV to revise the labeling again to “move the
19 following precaution statement “The safety and effectiveness of the G2 Filter System for
20 use as a retrievable or temporary filter have not been established” to the beginning of the
21 Precaution Section in bold font. Ex. A, Carr Decl. at ¶ 66.

22 **Objection. The use of the word “require” is misleading (the change was**
23 **requested and subject to negotiation as evidenced by prior labeling language**
24 **requests). Furthermore, statement contains inadmissible hearsay. Subject to said**
25 **objections, admit that the document relied upon attributes this statement to the FDA**
26 **reviewer.**

27 254. The FDA reviewer determined that BPV “adequately addressed” all of
28 FDA’s demands for additional information, and specific labeling and device name

1 changes, and recommended that FDA clear the G2 Filter as substantially equivalent to the
2 Recovery Filter with limitations. Ex. A, Carr Decl. at ¶ 66.

3 **Objection. The use of the word “demands” is misleading. Furthermore,**
4 **statement contains inadmissible hearsay. Subject to said objections, admit that the**
5 **document relied upon attributes this statement to the FDA reviewer.**

6 255. On August 26, 2005, BPV received a draft “substantial equivalence with
7 limitations” letter from the FDA that required BPV to have “permanent placement of the
8 G2 Filter System...prominently displayed in all labeling, pouch, box, and carton labels,
9 instructions for use, and other promotional materials, in close proximity to the trade name,
10 of a similar point size and in bold print.” Ex. A, Carr Decl. at ¶ 67.

11 **Admit.**

12 256. FDA requested BPV to review the language and provide written affirmation
13 of BPV’s acceptance of the FDA-mandated labeling. Ex. A, Carr Decl. at ¶ 67.

14 **Admit.**

15 257. On August 29, 2005, BPV reviewed the specific limitations language and
16 faxed to FDA written affirmation that BPV would revise its labeling to include the FDA-
17 mandated specific language. Ex. A, Carr Decl. at ¶ 67.

18 **Admit the document relied upon indicates a request to BPV to review the**
19 **language and acceptance of the language presented by FDA. Deny this was**
20 **“mandated.”**

21 258. On August 29, 2005, BPV sent the FDA an email attaching copies of
22 proposed revisions to the labeling and IFU for the G2® Filter that included language
23 conspicuously stating the device had been cleared for permanent placement only, and
24 again the alternative language regarding morbidly obese patients. Ex. A, Carr Decl. at ¶
25 68.

26 **Admit the relied upon document indicates review and acceptance. Deny this**
27 **was “mandated.”**
28

1 259. BPV thus sought clarification that the proposed labeling was sufficient to
2 meet the FDA's requirements. Ex. A, Carr Decl. at ¶ 68.

3 **Admit.**

4 260. On August 29, 2005, the FDA cleared the G2® Filter to be marketed for
5 permanent placement, subject to FDCA general and special controls, after reviewing all of
6 the data submitted by BPV, including the additional information and labeling changes
7 required by the FDA, and after determining that the G2® Filter was as safe and effective
8 as, and therefore substantially equivalent to, the Recovery® Filter for permanent
9 indication. Ex. A, Carr Decl. at ¶ 69.

10 **Admit.**

11 261. Because the FDA determined there was a reasonable likelihood that this
12 device would be used off-label for a retrievable indication, and that such use could cause
13 harm, the FDA limited the substantial equivalence finding, pursuant to 21 U.S.C. §
14 360c(i)(1)(E), and required BPV to include specific language in the G2® Filter System's
15 labeling and promotional materials stating: "The safety and effectiveness of the G2 Filter
16 System for use as a retrievable or temporary filter have not been established." Ex. A, Carr
17 Decl. at ¶ 69.

18 **Admit.**

19 **B. The EVEREST Study (G050134)**

20 262. On June 3, 2005, BPV sent the FDA a proposed draft of the clinical protocol
21 it planned to use for the clinical study required by the FDA to clear the G2® Filter for the
22 retrievable indication, which was called the EVEREST study. Ex. A, Carr Decl. at ¶ 70.

23 **Admit.**

24 263. "The purpose of the study is to assess the safety of the removal of the [G2®]
25 Filter." Ex. A, Carr Decl. at ¶ 70.

26 **Admit.**

27 264. On July 8, 2005, BPV submitted an original IDE submission to the FDA for
28 the EVEREST study. Ex. A, Carr Decl. at ¶ 71.

1 **Admit.**

2 265. On July 29, 2005, the FDA contacted BPV and indicated that the FDA
3 “planned to disapprove the IDE due to the implication in the protocol and informed
4 consent that the 510(k) was already cleared as a permanent filter.” Ex. A, Carr Decl. at ¶
5 72.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
7 **objection, admit that the document relied upon attributes this statement to the FDA.**

8 266. On August 5, 2005, BPV and the FDA had a telephone conference to
9 discuss some of the FDA’s questions and concerns regarding the IDE submission. Ex. A,
10 Carr Decl. at ¶ 73.

11 **Objection. This statement contains inadmissible hearsay. Subject to said**
12 **objection, admit that the document relied upon states that a telephone conference**
13 **occurred on August 5, 2005.**

14 267. After BPV assured the FDA that it was “committed to working with the
15 FDA to reach a consensus on the protocol and informed consent,” the FDA reconsidered
16 the disapproval of the IDE and indicated that it would grant conditional approval, subject
17 to BPV changing the protocol and informed consent. Ex. A, Carr Decl. at ¶ 73.

18 **Objection. This statement contains inadmissible hearsay. Subject to said**
19 **objection, admit that the document relied upon contains these statements.**

20 268. On August 8, 2005, the FDA granted BPV conditional approval of the IDE,
21 subject to BPV correcting certain deficiencies identified by the FDA. Ex. A, Carr Decl. at
22 ¶ 74.

23 **Admit.**

24 269. The FDA required BPV to change the study’s informed consent form,
25 change the study’s protocol, provide clarification of the definition of migration, and
26 change the manner in which study personnel were trained. Ex. A, Carr Decl. at ¶ 74.

27 **Admit that such changes were requested, not required.**

1 270. On August 25, 2005, BPV and the FDA had a conference call to address the
2 FDA's demands on August 8, 2005. Ex. A, Carr Decl. at ¶ 75.

3 **Objection. The use of the word "demands" is misleading. Subject to said**
4 **objection, admit that a conference was held.**

5 271. The FDA and BPV discussed the definition of migration as used in the
6 study. Ex. A, Carr Decl. at ¶ 75.

7 **Admit.**

8 272. The FDA accepted BPV's proposal to maintain the definition of migration
9 as movement of 2 cm or more. Ex. A, Carr Decl. at ¶ 75.

10 **Objection. Statement is misleading. Furthermore, the statement contains**
11 **inadmissible hearsay. According to the hearsay statements, the FDA accepted the**
12 **definition, but notes of the call indicate acceptance was conditioned on Bard agreeing**
13 **to collect data on all filter movement and evaluate any AEs potentially associated**
14 **with filter movement. Moreover, the FDA recognizes that "[f]ilter migration of less**
15 **than 2 cm can affect a filter's effectiveness" See Bard SOF Ex. A at Ex. 73.**

16 273. On October 3, 2005, BPV submitted its official response to the additional
17 information required by the FDA on August 8, 2005, which included the required changes
18 to the study's informed consent form, response justifying the study protocol, clarification
19 of the definition of migration, and changes to the manner in which study personnel are
20 trained. Ex. A, Carr Decl. at ¶ 76.

21 **Admit in part, deny in part or admit with clarification. Bard was addressing**
22 **"deficiencies" in the study pointed out by the FDA and also making modifications**
23 **recommended by its study investigator, which is not mentioned. See Bard SOF Ex. A**
24 **at Ex. 73 (BPV-17-01-00122848-49). Interactions with the FDA regarding**
25 **applications are a back and forth negotiation. See Ex. 11 at 92:1-4.**

26 274. On October 21, 2005, as evidenced in an internal BPV memorandum, the
27 FDA indicated to BPV that the filter retrieval data from the EVEREST study could readily
28 be used to support changing the indication for removal for both the femoral and jugular

1 delivery systems, and therefore including the Jugular delivery system in the study was
2 unnecessary. Ex. A, Carr Decl. at ¶ 77.

3 **Objection. The use of the word “demands” is misleading. Furthermore,**
4 **statement contains inadmissible hearsay. Subject to said objections, admit the**
5 **document relied upon attributes this statement to the FDA. Deny the document**
6 **indicates use of the data for both femoral and jugular delivery methods was the sole**
7 **reason the jugular delivery systems was unnecessary; the document relied upon**
8 **indicates the jugular delivery system was not ready and waiting to for its availability**
9 **did not meet the strategic purpose.**

10 275. On November 2, 2005, the FDA granted full approval of BPV’s IDE
11 application. Ex. A, Carr Decl. at ¶ 78.

12 **Admit.**

13 276. On December 2, 2005, BPV sent the FDA notice of IDE change. Ex. A,
14 Carr Decl. at ¶ 79.

15 **Admit that Bard corrected misprints in the IFU.**

16 277. The purpose of the notice was to inform the FDA of two
17 typographical/clerical changes to the clinical protocol, which did “not affect the validity
18 of the data or information resulting from the completion of the approved protocol, the
19 relationship of likely patient risk to benefit relied upon to approve the protocol, the
20 scientific soundness of the investigational plan, or the rights, safety, or welfare of the
21 human subjects involved in the investigation.” Ex. A, Carr Decl. at ¶ 79.

22 **Admit.**

23 278. On June 21, 2006, BPV sent the FDA an IDE supplement with an updated
24 list of investigators, pursuant to 21 C.F.R. § 812.150(b)(4). Ex. A, Carr Decl. at ¶ 80.

25 **Admit.**

26 279. Also on this date, BPV sent the FDA notification of an informed consent
27 violation, pursuant to 21 C.F.R. § 812.150(b)(8), with all required information, pursuant
28 21 C.F.R. § 812.150(a)(5). Ex. A, Carr Decl. at ¶ 80.

1 **Admit.**

2 280. In response to these violations, BPV ceased enrollment at the single affected
3 site and distributed a memorandum to all the clinical study sites and study monitors to
4 remind them of their responsibilities regarding informed consent. Ex. A, Carr Decl. at ¶
5 80.

6 **Admit.**

7 281. On July 11, 2006, BPV sent an IDE supplement to the FDA, proposing to
8 extend the study follow-up period from 6 months to 12 months and to increase the
9 enrollment by up to 50 additional patients. Ex. A, Carr Decl. at ¶ 81.

10 **Admit.**

11 282. BPV indicated that it wanted to make these proposed changes so that it
12 could obtain the necessary information for filing a future 510(k). Ex. A, Carr Decl. at
13 ¶ 81.

14 **Admit.**

15 283. On December 6, 2006, BPV sent a request to the FDA for an extension on
16 the due date for its annual progress report as required by 21 C.F.R. § 812.150(b)(5). Ex.
17 A, Carr Decl. at ¶ 82.

18 **Admit.**

19 284. BPV was anticipating that the first 30 filter retrievals would be completed
20 by March 30, 2007, and it wanted to include data from those retrievals in its annual report.
21 Ex. A, Carr Decl. at ¶ 82.

22 **Admit.**

23 285. On December 8, 2006, BPV sent the FDA an IDE supplement with an
24 updated list of investigators, pursuant to the requirements of 21 C.F.R. 812.150(b)(4). Ex.
25 A, Carr Decl. at ¶ 83.

26 **Admit.**

27 286. On February 2, 2007, BPV sent the FDA its annual progress report, pursuant
28 to the requirements of 21 C.F.R. 812.150(b)(5). Ex. A, Carr Decl. at ¶ 84.

1 **Admit.**

2 287. This report included extensive clinical data up to August 31, 2006, the date
3 of the 30th retrieval of a filter, and noted that no unanticipated adverse events had been
4 reported. Ex. A, Carr Decl. at ¶ 84.

5 **Admit in part, deny in part as misleading to the extent it suggests that no**
6 **anticipated adverse events were reported. The report states: "All reported adverse**
7 **events are consistent with those previously identified in the protocol and also**
8 **anticipated for IVC filter placement and retrieval." The report says most events are**
9 **associated with patient's pre-existing or intercurrent medical condition and not with**
10 **the RF. However, 4 caudal migrations ("anticipated adverse event") were noted**
11 **although three of four filters were successfully removed, which Bard fails to mention**
12 **focusing solely on the "unanticipated adverse events."**

13 288. On August 23, 2007, BPV sent the FDA another annual progress report,
14 pursuant to the requirements of 21 C.F.R. 812.150(b)(5). Ex. A, Carr Decl. at ¶ 85.

15 **Admit.**

16 289. This report included extensive clinical data up to May 25, 2007, and again,
17 no unanticipated adverse events had been reported. Ex. A, Carr Decl. at ¶ 85.

18 **Admit that the report included in clinical data; deny the assertion that it is**
19 **"extensive." See Bard SOF Ex. A at Ex. 83 (BPV-17-01-00123461); see also supra, at**
20 **¶ 287: 14% of patients experienced filter related adverse events.**

21 290. On September 21, 2007, the FDA reviewed the August 23, 2007 annual
22 progress report and required BPV to provide additional information. Ex. A, Carr Decl. at
23 ¶ 86.

24 **Deny. The FDA required Bard to provide additional information if it chose to**
25 **move forward with its application, but not because the FDA was asking for new**
26 **information that was not already required. For example, the FDA asked Bard to**
27 **clarify discrepancies in its adverse event reporting, clarify how it determined if an**
28 **adverse event is device or procedure-related and more detail on these adverse events**

1 of interest, and justify a 10% migration rate—all of which is information Bard
2 should have provided.

3 291. The FDA notified BPV of several requirements. Ex. A, Carr Decl. at ¶ 86.

4 **Deny. The FDA "determined that additional information is required. Please**
5 **address the following questions and concerns[.]" The FDA did not impose new or**
6 **additional requirements, but instead wanted questions and concerns answer because**
7 **the progress report was deficient/inadequate.**

8 292. The FDA required BPV to provide additional detailed information regarding
9 adverse events observed during the clinical study and reported in the progress report
10 (Question 1). Ex. A, Carr Decl. at ¶ 86.

11 **Deny. The FDA asked Bard to address discrepancies related to adverse event**
12 **reporting from the prior report to subsequent one.**

13 293. The FDA required BPV to provide a detailed summary of the incidence of
14 specific adverse events: caval injury or damage, caval occlusion, caval thrombosis, deep
15 vein thrombosis, filter embolization, filter fracture, filter migration, IVC penetration, and
16 pulmonary embolism (Question 2). Ex. A, Carr Decl. at ¶ 86.

17 **Admit this was requested, deny this was a new requirement; it is information**
18 **Bard could have provided and did not, resulting in this showing to the FDA.**

19 294. The FDA required BPV to provide an explanation of the incidence of filter
20 migration experienced during the clinical study as well as provide a comparison of
21 migration rates of the Recovery® and G2® Filters currently marketed (Question 3). Ex.
22 A, Carr Decl. at ¶ 86.

23 **Admit the FDA asked Bard to compare migration rates of Recovery and G2**
24 **devices. Deny the FDA asked Bard to explain why a 10% rate of device migration is**
25 **clinically acceptable, not to explain the incidence of migration experienced.**

26 295. The FDA required BPV to report the cumulative number of follow-up visits
27 conducted outside the study protocol and the number of patients who missed follow-up
28 visits (Question 4). Ex. A, Carr Decl. at ¶ 86.

1 **Admit.**

2 296. The FDA required BPV to provide a comparison of the incidence of
3 deployment related issues in the investigational G2® Filter as compared to the G2® Filter
4 currently marketed with the modifications to the delivery system that FDA cleared on
5 October 27, 2006 (Question 5). Ex. A, Carr Decl. at ¶ 86.

6 **Admit.**

7 297. The FDA required BPV to provide data regarding the appearance of the IVC
8 on imaging studies after filter retrieval, as well as the implant duration of the filters at
9 retrieval or attempted retrieval, which the FDA “considered essential for the analysis of
10 your data for the purposes of determining substantial equivalence for a future 510(k)
11 submission.” Ex. A, Carr Decl. at ¶ 86.

12 **Admit in part and deny in part. The FDA did not "require" Bard to provide**
13 **data related to the two items listed, but instead asked Bard to "give serious**
14 **consideration to the following item which are considered essential for the analysis of**
15 **your data for the purposes of determining substantial equivalence for a future 510(k)**
16 **submission."**

17 298. On October 25, 2007, BPV provided the additional information required by
18 the FDA in its September 21, 2007 letter. Ex. A, Carr Decl. at ¶ 87.

19 **Deny. Per Bard's own language on page 1 of its letter to the FDA, BPV "is**
20 **submitting, in triplicate, an IDE supplement in response to the deficiencies addressed**
21 **in the letter received September 21, 2007...." Bard SOF Ex. A at Ex. 85.**

22 299. In response to FDA’s demand (Question 1), BPV provided a tabulated list of
23 the adverse events reported since the February annual progress report. Ex. A, Carr Decl.
24 at ¶ 87.

25 **Objection. The use of the word “demand” is misleading. Subject to said**
26 **objection, admit that the document relied upon so states.**

1 300. In response to FDA’s demand (Question 2), BPV provided a detailed list
2 summarizing the adverse events observed during the study as well as a detailed list of the
3 specific incidents required by the FDA. Ex. A, Carr Decl. at ¶ 87.

4 **Admit with clarification. The FDA asked Bard to provide specificity regarding**
5 **adverse events that Bard could have and should have provided in the first place.**

6 301. In response to FDA’s demand (Question 3), BPV provided an explanation
7 for the incidence of migration observed during the clinical study, as well as the
8 comparative data required by the FDA. Ex. A, Carr Decl. at ¶ 87.

9 **Admit with clarification. Bard was asked to explain why the 10% migration**
10 **rate in the study is not clinically significant, not simply to explain the high rate.**

11 302. In response to FDA’s demand (Question 4), BPV provided a report of the
12 cumulative number of follow-up visits conducted outside the study protocol. Ex. A, Carr
13 Decl. at ¶ 87.

14 **Admit.**

15 303. In response to FDA’s demand (Question 5), BPV provided a report of the
16 deployment issues experienced with the filter during the clinical study, as well as the
17 comparative data required by the FDA. Ex. A, Carr Decl. at ¶ 87.

18 **Admit.**

19 304. On December 11, 2007, BPV and the FDA had a telephone conversation to
20 discuss closing out the EVEREST study and whether BPV could satisfy its final reporting
21 requirements by referencing the 510(k) submission that was then under review in
22 accordance with the FDA guidance document “Guidance on IDE Policies and
23 Procedures.” Ex. A, Carr Decl. at ¶ 88.

24 **Objection. This statement contains inadmissible hearsay as to what the FDA**
25 **is reported to have said and what the conversation was reported to entail, as the**
26 **document referenced is simply a Bard internal memo summarizing a conversation.**
27 **Subject to said objection, admit that Bard SOF Ex. A at Ex. 86 makes this**
28

1 **representation. Deny that the Guidance referenced was a “special control”**
 2 **applicable specifically to IVC filters under C.F.R. § 870.3375.**

3 305. The FDA indicated that BPV should wait until the 510(k) submission was
 4 completed, then “if 510(k) clearance is received, BPV can refer to the 510(k) and provide
 5 any additional information, such as investigational device disposition.” Ex. A, Carr Decl.
 6 at ¶ 88.

7 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 8 **is reported to have said and what the conversation was reported to entail, as the**
 9 **document referenced is simply a Bard internal memo summarizing a conversation.**
 10 **Subject to said objection, admit that Bard SOF Ex. A at Ex. 86 makes this**
 11 **representation. Deny that the FDA was requiring or mandating any action by Bard**
 12 **other than the standard method for 510(k) submission.**

13 306. On February 12, 2008, BPV sent its final report on the EVEREST study to
 14 the FDA, pursuant to 21 C.F.R. 812.150(b)(7). Ex. A, Carr Decl. at ¶ 89.

15 **Admit.**

16 307. The FDA received BPV’s final report and sent an acknowledgment of
 17 completion on March 12, 2008. Ex. A, Carr Decl. at ¶ 89.

18 **Admit.**

19 **C. G2® Filter System – Jugular/Subclavian Delivery Kit (K052578)**

20 308. On September 19, 2005, BPV submitted a Special 510(k) for its G2® Filter
 21 System – Jugular/Subclavian Delivery Kit to gain approval for a new delivery kit to the
 22 previously cleared G2® Filter System. Ex. A, Carr Decl. at ¶ 90.

23 **Admit.**

24 309. The previous version of the G2® Filter System (K050558) included a
 25 femoral delivery kit but not a jugular/subclavian delivery kit. Ex. A, Carr Decl. at ¶ 90.

26 **Admit.**

27 310. The filter that was the subject of this submission was identical to the
 28 predicate device. Ex. A, Carr Decl. at ¶ 90.

1 **Admit.**

2 311. Included in the 510(k) submission were results from 72 *in-vitro* bench tests
3 conducted by BPV on the G2® Filter Jugular/Subclavian delivery system. Ex. A, Carr
4 Decl. at ¶ 90.

5 **Admit that 510(k) submission (Bard SOF Ex. A at Ex. 89) included a table**
6 **summarizing the description of a number of tests allegedly performed on the G2 and**
7 **stating “Pass” under the heading “Results.” Deny that Bard provided any actual**
8 **data setting forth results. *Id.* Further deny that all data was directly from testing of**
9 **the G2 device; some data was referenced and incorporated from previous Bard**
10 **510(k) applications, specifically the Simon Nitinol Filter application in 1990**
11 **(K894703). *Id.* at Ex. 9 (BPV-17-01-00057770).**

12 312. This testing was performed in conformance with the FDA guidance
13 document: “Guidance for Cardiovascular Intravascular Filter 510(k) Submission.” Ex. A,
14 Carr Decl. at ¶ 90.

15 **Deny. Bard states in the document "Testing was also performed with**
16 **consideration to the special control documents, FDA's ‘Guidance for Intravascular**
17 **Filter 510(k) Submissions’”, NOT "in conformance with" as stated in this SOF.**
18 **Bard SOF Ex. A at Ex. 42 (BPV-17-01-00125689-90). In addition, the referenced**
19 **Guidance clearly states it “describes a means by which cardiovascular intravascular**
20 **filter devices may comply with the requirement of special controls for Class II**
21 **devices.” It also states that the “document is intended to provide guidance. It**
22 **represents the Agency’s current thinking on the above. It does not create or confer**
23 **any rights for or on any person and does not operate to bind FDA or the public. An**
24 **alternative approach may be used if such approach satisfies the requirements of the**
25 **applicable statute, regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-**
26 **00034595).**

27 313. BPV conducted a risk analysis, a Risk Assessment and Design Failure
28 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO

1 14971:2000, Medical Devices – Application of risk management to medical devices and
 2 BS EN 1441:1998, Medical Devices-Risk Analysis, to assure that risks posed by the
 3 design were acceptable. Ex. A, Carr Decl. at ¶ 90.

4 **Admit with clarification. This is not discussed on page 11 of the document as**
 5 **cited in the Carr Declaration, but on page 15. The cited document does not say that**
 6 **BPV conducted these tests in accordance with the ISO cited, but instead "in**
 7 **accordance with internal procedures based on ISO 14971:2000."**

8 **Deny. The referenced document, Bard SOF at Ex. 89, states that the DFMEA**
 9 **was "performed in accordance with internal procedures based on ISO**
 10 **14971:2000...." It is unclear whether the internal Bard standards wholesale adopted**
 11 **the referenced ISO standard. Further deny that the ISO referenced is a "special**
 12 **control" applicable to IVC filters under C.F.R. § 870.3375.**

13 314. The design verification and validation were performed in conformance with:
 14 FDA Special Controls guidance document, "Guidance for Cardiovascular Intravascular
 15 Filter 510(k) Submission;" BS EN 12006-3:1999 entitled, "Non-Active Surgical Implants
 16 – Particular Requirements for Cardiac and Vascular Implants – Part 3: Endovascular
 17 Devices;" FDA guidance document, Design Control Guidance for Medical Device
 18 Manufacturers, dated March 11, 1997; and the design control requirements under 21 CFR
 19 § 820.30. Ex. A, Carr Decl. at ¶ 90.

20 **Deny with exception of 90(iii)(4). The document states these tests were**
 21 **"performed with consideration to" Bard SOF Ex. A at Ex. 42 (BPV-17-01-**
 22 **00125689). Page 58, which Carr cites to support 90(iii)(4), does state that the Glen**
 23 **Falls Operation "is in conformance with the design control requirements as specified**
 24 **in 21 CFR 820.30." *Id.***

25 **In addition, the referenced document section states the "verification and**
 26 **validation of the design changes were performed with consideration to" the stated**
 27 **guidances, not "in conformance with." *Id.* Further deny that BS EN 12006-3:1999**
 28 **entitled, "Non-Active Surgical Implants – Particular Requirements for Cardiac and**

Vascular Implants – Part 3: Endovascular Devices;” FDA guidance document, Design Control Guidance for Medical Device Manufacturers, dated March 11, 1997; and the design control requirements under 21 C.F.R. § 820.30 are “special controls” specifically applicable to IVC filters under C.F.R. § 870.3375. Lastly, “Guidance for Cardiovascular Intravascular Filter 510(k) Submission” clearly states it “describes a means by which cardiovascular intravascular filter devices may comply with the requirement of special controls for Class II devices.” It also states that the “document is intended to provide guidance. It represents the Agency’s current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-00034595).

315. The submission also included results from biocompatibility testing conducted by BPV in conformance with ISO/AAMI 10993-1, as well as packaging testing, sterilization testing, and shelf-life testing. Ex. A, Carr Decl. at ¶ 90.

Admit that the document relied upon so states. Deny that biocompatibility testing was performed on the subject device, as the document instead references the applicability of the testing on the predicate device. *Id.* Further deny that the ISO standard referenced is specific to Bard IVC filters or retrievable filters generally.

316. The submission also included proposed labeling for the G2® Filter Jugular/Subclavian Delivery System in conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 90.

Admit the 510(k) contained a copy of the proposed IFU for the subject device and schematics of “pouches” containing the delivery system. Deny that 510(k) contained a “labeling” which includes promotional materials, communications, etc. Bard SOF Ex. A at 32-48. Further deny that 21 C.F.R. § 807.87 establishes any “special control” applicable to IVC filters under C.F.R. § 870.3375; instead, that regulation simply states the information required for a premarket notification.

1 317. The submission also included a summary of safety and effectiveness
2 information upon which a substantial equivalence determination could be based as
3 required by the Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr
4 Decl. at ¶ 90.

5 **Admit.**

6 318. On September 21, 2005, BPV submitted additional information to the FDA
7 to correct certain misprints and labeling mistakes in its September 19, 2005 submission.
8 Ex. A, Carr Decl. at ¶ 91.

9 **Admit.**

10 319. On October 13, 2005, the FDA emailed BPV requesting a telephone
11 conference to discuss the FDA's concerns about BPV's submission. Ex. A, Carr Decl. at
12 ¶ 92.

13 **Admit.**

14 320. On October 14, 2005, the FDA and BPV had a teleconference to discuss the
15 FDA's concerns. Ex. A, Carr Decl. at ¶ 93.

16 **Admit.**

17 321. The FDA and BPV discussed the modifications in the filter loading, storage,
18 and configuration of the Jugular/Subclavian Delivery System as compared to the predicate
19 G2® Filter Femoral Delivery System. Ex. A, Carr Decl. at ¶ 93.

20 **Objection. This statement contains inadmissible hearsay as to what the FDA**
21 **is reported to have said and what the conversation was reported to entail, as the**
22 **document referenced is simply a Bard internal memo summarizing a conversation.**
23 **Subject to said objection, admit that that Bard SOF Ex. A at Ex. 92 makes this**
24 **representation. Deny that the FDA was requiring or mandating any action by Bard**
25 **other than complying with the standard requirements for 510(k) submission.**

26 322. The FDA stated it would require BPV to include additional information in
27 the submission, specifically "a description of each part of the delivery system, a
28 description of how the filter is loaded, stored, and delivered, a comparison of steps with

1 the predicate device in tabular format, and any type of animation or simulation footage to
2 help visually clarify the device.” Ex. A, Carr Decl. at ¶ 93.

3 **Objection. This statement contains inadmissible hearsay as to what the FDA**
4 **is reported to have said and what the conversation was reported to entail, as the**
5 **document referenced is simply a Bard internal memo summarizing a conversation.**
6 **Subject to said objection, admit that Bard SOF Ex. A at Ex. 92 makes this**
7 **representation. Deny that the FDA was requiring or mandating any action by Bard**
8 **other than complying with the standard requirements for 510(k) submission, as the**
9 **requested information should have been provided in the first place.**

10 323. The FDA also discussed the Risk Analysis section of the submission and
11 indicated that BPV “should show the associated risk for each device change and the
12 testing that was conducted in response to each risk.” Ex. A, Carr Decl. at ¶ 93.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
14 **is reported to have said and what the conversation was reported to entail, as the**
15 **document referenced is simply a Bard internal memo summarizing a conversation.**
16 **Subject to said objection, admit that Bard SOF Ex. A at Ex. 92 makes this**
17 **representation. Deny that the FDA was requiring or mandating any action by Bard**
18 **other than complying with the standard requirements for 510(k) submission, as the**
19 **requested information should have been provided in the first place.**

20 324. The FDA also stated it would require BPV to add clarification as to why
21 new tests were performed for shelf-life testing, and add clarifications on any changes to
22 the package labeling. Ex. A, Carr Decl. at ¶ 93.

23 **Objection. This statement contains inadmissible hearsay as to what the FDA**
24 **is reported to have said and what the conversation was reported to entail, as the**
25 **document referenced is simply a Bard internal memo summarizing a conversation.**
26 **Subject to said objection, deny. Bard SOF Ex. A at Ex. 92 states that the FDA**
27 **“requested” the clarifications stated in the SOF. Further deny that the FDA was**
28 **requiring or mandating any action by Bard other than complying with the standard**

1 **requirements for 510(k) submission, as the requested information should have been**
2 **provided in the first place.**

3 325. The FDA further stated it would require BPV to provide more information
4 relating to the biocompatibility section of the submission in a biocompatibility table that
5 FDA would send to BPV following the conference. Ex. A, Carr Decl. at ¶ 93.

6 **Objection. This statement contains inadmissible hearsay as to what the FDA**
7 **is reported to have said and what the conversation was reported to entail, as the**
8 **document referenced is simply a Bard internal memo summarizing a conversation.**
9 **Subject to said objection, deny. Bard SOF Ex. A at Ex. 92 states that the FDA**
10 **“requested” the information stated in the SOF. Further deny that the FDA was**
11 **requiring or mandating any action by Bard other than complying with the standard**
12 **requirements for 510(k) submission, as the requested information should have been**
13 **provided in the first place.**

14 326. In a follow-up email that same day, the FDA summarized its formal
15 demands for additional information. Ex. A, Carr Decl. at ¶ 94.

16 **Deny. The FDA was not requesting “additional information;” instead, the**
17 **FDA was placing Bard’s 510(k) application on hold until it cured “deficiencies” in**
18 **that submission. Bard SOF Ex. A at Ex. 93. Further deny that the FDA was**
19 **requiring or mandating any action by Bard other than complying with the standard**
20 **requirements for 510(k) submission, as the requested information should have been**
21 **provided in the first place.**

22 327. The FDA required BPV to explain the modifications in greater detail,
23 including “a) a description of each part of the delivery catheter and its associated function;
24 b) step-by-step instructions for how the filter is loaded into the delivery catheter and
25 deployed; and c) a comparison in tabular format between the loading and deployment of
26 the subject device and the predicate device.” (Question 1). Ex. A, Carr Decl. at ¶ 94.

27 **Admit with clarification that the FDA was merely asking Bard to cure**
28 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**

1 **action by Bard other than complying with the standard requirements for 510(k)**
2 **submission.**

3 328. The FDA also required BPV to provide “additional information regarding
4 the risk analysis...in order to determine that the modifications you are requesting do not
5 affect the safety and effectiveness of the device.” (Question 2). Ex. A, Carr Decl. at ¶ 94.

6 **Admit with clarification that the FDA was merely asking Bard to cure**
7 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
8 **action by Bard other than complying with the standard requirements for 510(k)**
9 **submission.**

10 329. The FDA also required BPV to “[I]dentify and list any risks associated with
11 each modification, the verification/validation testing conducted to assess the identified
12 risks for each modification, and an explanation for why the testing conducted mitigates
13 the identified risk.” (Question 2). Ex. A, Carr Decl. at ¶ 94.

14 **Admit with clarification that the FDA was merely asking Bard to cure**
15 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
16 **action by Bard other than complying with the standard requirements for 510(k)**
17 **submission.**

18 330. The FDA also required BPV to provide “additional information...to
19 determine that the testing conducted supports the shelf life of the subject device,” and
20 required BPV to provide specific testing and acceptance criteria (Question 3). Ex. A, Carr
21 Decl. at ¶ 94.

22 **Admit with clarification that the FDA was merely asking Bard to cure**
23 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
24 **action by Bard other than complying with the standard requirements for 510(k)**
25 **submission.**

26 331. The FDA also required BPV to summarize the biocompatibility testing
27 within a biocompatibility testing results table provided by the FDA (Question 4). Ex. A,
28 Carr Decl. at ¶ 94.

1 **Admit with clarification that the FDA was merely asking Bard to cure**
2 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
3 **action by Bard other than complying with the standard requirements for 510(k)**
4 **submission.**

5 332. The FDA also required BPV to provide a redlined copy of labeling that BPV
6 modified from the predicate device (Question 5). Ex. A, Carr Decl. at ¶ 94.

7 **Admit with clarification that the FDA was merely asking Bard to cure**
8 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
9 **action by Bard other than complying with the standard requirements for 510(k)**
10 **submission.**

11 333. Also on that same day, the FDA mailed a letter to BPV informing BPV of
12 the FDA's decision to put the submission on a 30 day hold pending BPV's response to the
13 FDA's requests, and indicating that if BPV did not respond with the additional
14 information within 30 days, the 510(k) submission would be withdrawn. Ex. A, Carr
15 Decl. at ¶ 95.

16 **Admit with clarification that the FDA was merely asking Bard to cure**
17 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
18 **action by Bard other than complying with the standard requirements for 510(k)**
19 **submission.**

20 334. On October 25, 2005, BPV provided the additional information required by
21 FDA in its October 14, 2005 email. Ex. A, Carr Decl. at ¶ 96.

22 **Admit with clarification that the FDA was merely asking Bard to cure**
23 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
24 **action by Bard other than complying with the standard requirements for 510(k)**
25 **submission.**

26 335. In response to FDA's demand (Question 1), BPV provided a detailed
27 explanation of the modifications of the subject device. Ex. A, Carr Decl. at ¶ 96.
28

1 **Admit with clarification that the FDA was merely asking Bard to cure**
2 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
3 **action by Bard other than complying with the standard requirements for 510(k)**
4 **submission.**

5 336. In response to FDA's demand (Question 2), BPV provided a detailed
6 explanation of the risk analysis conducted for the subject device, including a table
7 describing the risks associated with the modifications, the testing that was performed, and
8 an explanation of how such testing mitigated this risk. Ex. A, Carr Decl. at ¶ 96.

9 **Admit with clarification that the FDA was merely asking Bard to cure**
10 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
11 **action by Bard other than complying with the standard requirements for 510(k)**
12 **submission.**

13 337. In response to FDA's demand (Question 3), BPV provided specific testing
14 and acceptance criteria conducted on the subject device regarding shelf-life, as well as
15 comparative testing performed on the predicate device. Ex. A, Carr Decl. at ¶ 96.

16 **Admit with clarification that the FDA was merely asking Bard to cure**
17 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
18 **action by Bard other than complying with the standard requirements for 510(k)**
19 **submission.**

20 338. In response to FDA's demand (Question 4), BPV provided a summary of
21 biocompatibility testing conducted on the subject device, including the completion of the
22 biocompatibility testing results table provided by the FDA. Ex. A, Carr Decl. at ¶ 96.

23 **Admit with clarification that the FDA was merely asking Bard to cure**
24 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
25 **action by Bard other than complying with the standard requirements for 510(k)**
26 **submission.**

27 339. In response to FDA's demand (Question 5), BPV responded that no
28 significant changes were made to the predicate IFU, and provided a redlined copy of the

1 labeling that BPV modified from the predicate device (Question 5). Ex. A, Carr Decl. at ¶
2 96.

3 **Admit with clarification that the FDA was merely asking Bard to cure**
4 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
5 **action by Bard other than complying with the standard requirements for 510(k)**
6 **submission.**

7 340. On November 14, 2005, the FDA and BPV had another conference call to
8 discuss the FDA's review of BPV's submission. Ex. A, Carr Decl. at ¶ 97.

9 **Admit.**

10 341. The FDA stated it still required additional information regarding risk
11 analysis directing BPV to clarify whether the test protocols and acceptance criteria in "the
12 original submission were the same as previous tests protocols and acceptance criteria
13 previously performed on the predicate device." Ex. A, Carr Decl. at ¶ 97.

14 **Objection. This statement contains inadmissible hearsay as to what the FDA**
15 **is reported to have said and what the conversation was reported to entail, as the**
16 **document referenced is simply a Bard internal memo summarizing a conversation.**
17 **Subject to said objection, deny. Bard SOF Ex. A at Ex. 96 states that the FDA**
18 **"asked if the tests protocol and acceptance criteria described ... in the original**
19 **submission were the same" as those performed on the predicate device – there was**
20 **no reference to the FDA "requiring" anything. Further deny that the FDA was**
21 **requiring or mandating any action by Bard other than complying with the standard**
22 **requirements for 510(k) submission. Lastly, it is important to clarify that the FDA**
23 **was merely continuing to ask Bard to cure deficiencies in its initial 510(k).**

24 342. On November 16, 2005, BPV submitted the required information to the
25 FDA, clarifying its previous response regarding the risk analysis testing conducted on the
26 subject device. Ex. A, Carr Decl. at ¶ 98.

27 **Admit with clarification that the FDA was merely asking Bard to cure**
28 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**

1 **action by Bard other than complying with the standard requirements for 510(k)**
 2 **submission.**

3 343. On November 25, 2005, the FDA cleared the new G2® Filter
 4 Jugular/Subclavian Delivery Kit for market, subject to the FDCA general and special
 5 controls, with the usual limitations on labeling it for permanent placement only, after
 6 reviewing the information provided in the 510(k) submission, as well as all additional
 7 information provided in response to FDA's requests, and finding the device substantially
 8 equivalent to the G2® Filter System – Femoral Delivery Kit. Ex. A, Carr Decl. at ¶ 99.

9 **Admit.**

10 **D. G2 Filter System for Permanent Indication – Femoral Delivery Kit**
 11 **(K062887)**

12 344. On September 25, 2006, BPV submitted a Special 510(k) for the G2 Filter
 13 System – Femoral Delivery Kit, which proposed changes to the delivery system only. Ex.
 14 A, Carr Decl. at ¶ 100.

15 **Admit.**

16 345. BPV proposed a new spline design that was intended to improve
 17 deployment accuracy and to prevent the filter hooks from sticking in the tip of the sheath
 18 during deployment. Ex. A, Carr Decl. at ¶ 100.

19 **Admit.**

20 346. Included in the 510(k) submission were results from 7 *in-vitro* bench tests
 21 conducted by BPV on the G2® Filter Jugular/Subclavian delivery system, including
 22 Pusher Wire and Spline Tensile Strength, Deployment Accuracy, Deployment Force,
 23 Simulated Use – Bench Top, Simulated Use – Acute Animal Study, Deployment
 24 Configuration, and Filter Hook Dislodgment. Ex. A, Carr Decl. at ¶ 100.

25 **Admit that the 510(k) submission (Bard SOF Ex. A at Ex. 99) included a table**
 26 **summarizing the description of a number of tests allegedly performed and stating**
 27 **“Pass” under the heading “Results.” Deny that Bard provided any actual data**
 28 **setting forth results. *See id.***

1 347. BPV conducted a risk analysis, a Risk Assessment and Design Failure
 2 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO
 3 14971:2000, Medical Devices – Application of risk management to medical devices, to
 4 assure that risks posed by the design were acceptable. Ex. A, Carr Decl. at ¶ 100.

5 **Deny. The document relied upon (Bard SOF Ex. A at Ex. 99), states that the**
 6 **DFMEA was “performed in accordance with internal procedures based on ISO**
 7 **14971:2000....” It is unclear whether the internal Bard standards wholesale adopted**
 8 **the referenced ISO standard. Further deny that the ISO referenced is a “special**
 9 **control” applicable to IVC filters under CFR 870.3375.**

10 348. This analysis did not identify any new types of safety or effectiveness
 11 issues. Ex. A, Carr Decl. at ¶ 100.

12 **Admit that is what the document states, but lack the information necessary to**
 13 **admit or deny the accuracy of that conclusion.**

14 349. The design verification and validation were performed in conformance with
 15 FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular
 16 Filter 510(k) Submission;” FDA’s “510(k) Sterility Review Guidance and Revision of
 17 2/12/90 (K90-1),” FDA’s “Use of International Standards Organizations ISO 10993
 18 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;” BS EN 12006-
 19 3:1999 entitled, “Non-Active Surgical Implants – Particular Requirements for Cardiac and
 20 Vascular Implants – Part 3: Endovascular Devices;” FDA guidance document, Design
 21 Control Guidance for Medical Device Manufacturers, dated March 11, 1997; and the
 22 design control requirements under 21 CFR § 820.30. Ex. A, Carr Decl. at ¶ 100.

23 **Deny. The referenced document section states the “verification and validation**
 24 **of the design changes were performed with consideration to” the stated guidances,**
 25 **not “in conformance with.” Bard SOF Ex. A at Ex. 99 at 20-21. Further deny that**
 26 **BS EN 12006-3:1999 entitled, “Non-Active Surgical Implants – Particular**
 27 **Requirements for Cardiac and Vascular Implants – Part 3: Endovascular Devices;”**
 28 **FDA guidance document, Design Control Guidance for Medical Device**

1 **Manufacturers, dated March 11, 1997; and the design control requirements under**
 2 **21 CFR § 820.30 are “special controls” specifically applicable to IVC filters under**
 3 **CFR 870.3375. Additionally, “Guidance for Cardiovascular Intravascular Filter**
 4 **510(k) Submission” clearly states it “describes a means by which cardiovascular**
 5 **intravascular filter devices may comply with the requirement of special controls for**
 6 **Class II devices.” It also states that the “document is intended to provide guidance. It**
 7 **represents the Agency’s current thinking on the above. It does not create or confer**
 8 **any rights for or on any person and does not operate to bind FDA or the public. An**
 9 **alternative approach may be used if such approach satisfies the requirements of the**
 10 **applicable statute, regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-**
 11 **00034595). Lastly, deny that “510(k) Sterility Review Guidance and Revision of**
 12 **2/12/90 (K90-1),” or “Use of International Standards Organizations ISO 10993**
 13 **Biological Evaluation of Medical Devices Part I: Evaluation and Testing” are**
 14 **specific to Bard IVC filters or retrievable filters generally.**

15 350. The submission also included were results from biocompatibility testing
 16 conducted by BPV in conformance to ISO 10993-1:2003, Biological Evaluation of
 17 Medical Devices – Part I: Evaluation and Testing. Ex. A, Carr Decl. at ¶ 100.

18 **Deny. The referenced biocompatibility testing was performed on the**
 19 **predicate device, not the subject device. Bard SOF Ex. A at Ex. 99, p. 27. In fact,**
 20 **the document relied upon specifically states “no additional biocompatibility testing**
 21 **was performed” on the subject device. *Id.* Further deny that the ISO standard**
 22 **referenced is specific to Bard IVC filters or retrievable filters generally.**

23 351. Also included were results from packaging testing, sterilization testing, and
 24 shelf-life testing. Ex. A, Carr Decl. at ¶ 100.

25 **Deny. The referenced testing was performed on the predicate device, not the**
 26 **subject device. Bard SOF Ex. A at Ex. 99, pp. 25-27. Deny that Bard provided any**
 27 **actual data setting forth results of the testing performed on the predicate device. *See***
 28 ***id.***

1 352. Also included was proposed labeling for the G2® Filter Femoral Delivery
2 System in conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 100.

3 **Admit the 510(k) contained a copy of the proposed IFU for the subject device**
4 **and schematics of “pouches” containing the delivery system. Deny that 510(k)**
5 **contained a “labeling” which includes promotional materials, communications, etc.**
6 **Bard SOF Ex. A at Ex. 99. Further deny that 21 C.F.R. § 807.87 establishes any**
7 **“special control” applicable to IVC filters under C.F.R. § 870.3375; instead, that**
8 **regulation simply states the information required for a premarket notification.**

9 353. Also included was a summary of the safety and effectiveness information
10 upon which a substantial equivalence determination could be based as required by the
11 Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 100.

12 **Admit.**

13 354. On October 26, 2006, the FDA cleared the modified G2® Filter Femoral
14 Delivery Kit for market, subject to the general controls and special controls under the
15 FDCA, with the usual limitations on labeling it for permanent placement only, after
16 reviewing the information provided in the 510(k) submission, and finding the device
17 substantially equivalent to the G2® Filter System – Femoral Delivery Kit. Ex. A, Carr
18 Decl. at ¶ 101.

19 **Admit.**

20 E. G2 Filter System for Removable Indication– Femoral and
21 Jugular/Subclavian Delivery Kits (K073090)

22 355. On December 4, 2006, BPV and the FDA had a teleconference to discuss
23 BPV’s strategy for its future traditional 510(k) for the G2® Filter System for removable
24 indication that was currently being evaluated under the EVEREST clinical study. Ex. A,
25 Carr Decl. at ¶ 102.

26 **Admit.**

27 **Objection. This statement contains inadmissible hearsay as to what the FDA**
28 **is reported to have said and what the conversation was reported to entail, as the**

1 **document referenced is simply a Bard internal memo summarizing a conversation.**
2 **Subject to said objection, deny that the document relied upon references the**
3 **EVEREST study or supports the SOF as to the portion on that study. Admit that**
4 **Bard SOF Ex. A at Ex. 101 makes the remainder of the representation.**

5 356. BPV proposed filing one traditional 510(k) using two predicate devices
6 (G2® Filter System – Femoral Delivery (K062887) and G2® Filter System –
7 Jugular/Subclavian Delivery Kit (K052578)) and one subject device. Ex. A, Carr Decl. at
8 ¶ 102.

9 **Objection. This statement contains inadmissible hearsay as to what the FDA**
10 **is reported to have said and what the conversation was reported to entail, as the**
11 **document referenced is simply a Bard internal memo summarizing a conversation.**
12 **Subject to said objection, admit that the document relied upon makes this**
13 **representation.**

14 357. The FDA agreed with this strategy and noted that BPV should emphasize
15 that the two delivery systems have not changed since the last cleared submissions. Ex. A,
16 Carr Decl. at ¶ 102.

17 **Objection. This statement contains inadmissible hearsay as to what the FDA**
18 **is reported to have said and what the conversation was reported to entail, as the**
19 **document referenced is simply a Bard internal memo summarizing a conversation.**
20 **Subject to said objection, admit that the document relied upon makes this**
21 **representation.**

22 358. BPV also proposed that it submit only the testing applicable to the
23 removability of the filter and refer the reviewer to previous submissions for test data
24 related to the filter and the delivery systems. Ex. A, Carr Decl. at ¶ 102.

25 **Objection. This statement contains inadmissible hearsay as to what the FDA**
26 **is reported to have said and what the conversation was reported to entail, as the**
27 **document referenced is simply a Bard internal memo summarizing a conversation.**
28

1 **Subject to said objection, admit that the document relied upon makes this**
 2 **representation.**

3 359. The FDA agreed with this approach and suggested BPV include a summary
 4 table for all testing that has been completed and in which previous submissions the data
 5 was presented. Ex. A, Carr Decl. at ¶ 102.

6 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 7 **is reported to have said and what the conversation was reported to entail, as the**
 8 **document referenced is simply a Bard internal memo summarizing a conversation.**
 9 **Subject to said objection, admit that the document relied upon makes this**
 10 **representation.**

11 360. On October 31, 2007, BPV submitted its over 1500-page traditional 510(k)
 12 for the G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits, seeking to
 13 remove the limitation on its previous 510(k) clearance for the device and obtain clearance
 14 for removable indication. Ex. A, Carr Decl. at ¶ 103.

15 **Admit.**

16 361. Included in the 510(k) submission were results from the previously reported
 17 extensive *in-vitro* bench testing and *in-vivo* animal testing, as well as the extensive clinical
 18 results of the EVEREST clinical study, including all testing reports and the clinical study
 19 materials that supported removability. Ex. A, Carr Decl. at ¶ 103.

20 **Admit that the 510(k) submission (Bard SOF Ex. A at Ex. 102) included**
 21 **“summaries” of a number of tests allegedly performed. Deny that Bard provided the**
 22 **actual data setting forth results or supporting its conclusions. *See id.* Further deny**
 23 **that the testing performed was “extensive.”**

24 362. BPV conducted a risk analysis, a Risk Assessment and Design Failure
 25 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO
 26 14971:2000, Medical Devices – Application of risk management to medical devices, to
 27 assure that risks posed by the design were acceptable. Ex. A, Carr Decl. at ¶ 103.

1 **Deny.** The referenced document, Bard SOF Ex. A at Ex. 99, states that the
 2 **DFMEA was “performed in accordance with internal procedures based on ISO**
 3 **14971:2000....” It is unclear whether the internal Bard standards wholesale adopted**
 4 **the referenced ISO standard. Further deny that the ISO referenced is a “special**
 5 **control” applicable to IVC filters under CFR 870.3375.**

6 363. The design verification and validation were performed in conformance with:
 7 FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular
 8 Filter 510(k) Submission;” FDA’s “510(k) Sterility Review Guidance and Revision of
 9 2/12/90 (K90-1);” FDA’s “Use of International Standards Organizations ISO 10993
 10 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;” Bluebook
 11 Memorandum G95-1, Use of ISO 10993 Biological Evaluation of Medical Devices Part 1:
 12 Evaluation and Testing; BS EN 12006-3:1999 entitled, “Non-Active Surgical Implants –
 13 Particular Requirements for Cardiac and Vascular Implants – Part 3: Endovascular
 14 Devices;” FDA guidance document, Design Control Guidance for Medical Device
 15 Manufacturers, dated March 11, 1997; and the design control requirements under 21 CFR
 16 § 820.30. Ex. A, Carr Decl. at ¶ 103.

17 **Deny.** Much of the testing referenced was performed on the predicate device,
 18 **not the subject device, and the prior 510(k)’s stated the “verification and validation**
 19 **of the design changes were performed with consideration to” the stated guidances,**
 20 **not “in conformance with.” Bard SOF Ex. A at Ex. 102; *see also id.* at Ex. 99 at 20-**
 21 **21. Further deny that BS EN 12006-3:1999 entitled, “Non-Active Surgical Implants**
 22 **– Particular Requirements for Cardiac and Vascular Implants – Part 3:**
 23 **Endovascular Devices;” FDA guidance document, Design Control Guidance for**
 24 **Medical Device Manufacturers, dated March 11, 1997; and the design control**
 25 **requirements under 21 C.F.R. § 820.30 are “special controls” specifically applicable**
 26 **to IVC filters under C.F.R. § 870.3375. Additionally, “Guidance for Cardiovascular**
 27 **Intravascular Filter 510(k) Submission” clearly states it “describes a means by which**
 28 **cardiovascular intravascular filter devices may comply with the requirement of**

1 special controls for Class II devices.” It also states that the “document is intended to
 2 provide guidance. It represents the Agency’s current thinking on the above. It does
 3 not create or confer any rights for or on any person and does not operate to bind the
 4 FDA or the public. An alternative approach may be used if such approach satisfies
 5 the requirements of the applicable statute, regulations, or both.” Bard SOF Ex. F at
 6 1 (BPV-17-01-00034595). Lastly, deny that “510(k) Sterility Review Guidance and
 7 Revision of 2/12/90 (K90-1),” or “Use of International Standards Organizations ISO
 8 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing” are
 9 specific to Bard IVC filters or retrievable filters generally.

10 364. Also included in the submission were results from biocompatibility and
 11 toxicity testing conducted by BPV in conformance with: ISO 10993-1:2003, Biological
 12 Evaluation of Medical Devices – Part I: Evaluation and Testing; Blue Book
 13 memorandum G95-1, Use of ISO10993 Biological evaluation of Medical Devices Part 1:
 14 Evaluation and Testing; and Guidance for Cardiovascular Intravascular Filter 510(k)
 15 Submissions (November 26, 1999). Ex. A, Carr Decl. at ¶ 103.

16 **Deny.** The referenced biocompatibility testing was performed on the
 17 predicate device, not the subject device. Bard SOF Ex. A at Ex. 102 at 46. Further
 18 deny that Bard provided the actual data supporting its conclusions; instead, the
 19 510(k) simply states in conclusory fashion that testing was done and the predicate
 20 device met the criteria. *Id.* Further deny that the ISO standard referenced is
 21 specific to Bard IVC filters or retrievable filters generally. Lastly, deny that any
 22 action was taken “in conformance with” the “Guidance for Cardiovascular
 23 Intravascular Filter 510(k) Submission”, as that guidance clearly states it “describes
 24 a means by which cardiovascular intravascular filter devices may comply with the
 25 requirement of special controls for Class II devices.” It also states that the
 26 “document is intended to provide guidance. It represents the Agency’s current
 27 thinking on the above. It does not create or confer any rights for or on any person
 28 and does not operate to bind FDA or the public. An alternative approach may be

1 **used if such approach satisfies the requirements of the applicable statute,**
 2 **regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-00034595).**

3 365. Also included were results from packaging testing, sterilization testing,
 4 shelf-life testing, and MRI Compatibility testing. Ex. A, Carr Decl. at ¶ 103.

5 **Deny. The referenced testing was performed on the predicate device, not the**
 6 **subject device. Bard SOF Ex. A at Ex. 102 at 43-45. Deny that Bard provided any**
 7 **actual data setting forth results of the testing performed on the predicate device. *Id.***

8 366. Also included was proposed labeling for the G2® Filter Femoral and
 9 Jugular/Subclavian Delivery System in conformance with 21 CFR § 807.87(e). Ex. A,
 10 Carr Decl. at ¶ 103.

11 **Admit the 510(k) contained a copy of the proposed IFU for the subject device**
 12 **and schematics of “pouches” containing the delivery system. Deny that 510(k)**
 13 **contained a “labeling” which includes promotional materials, communications, etc.**
 14 **Bard SOF Ex. A at Ex. 102. Further deny that 21 C.F.R. § 807.87 establishes any**
 15 **“special control” applicable to IVC filters under C.F.R. § 870.3375; instead, that**
 16 **regulation simply states the information required for a premarket notification.**

17 367. Also included was a summary of the safety and effectiveness information
 18 upon which a substantial equivalence determination could be based as required by the
 19 Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 103.

20 **Admit.**

21 368. On January 15, 2008, the FDA cleared the G2® Filter for retrievable
 22 indication, subject to the general and special controls of the FDCA, after reviewing the
 23 extensive *in-vitro* and *in-vivo* non-clinical testing, as well as the extensive clinical testing
 24 data that the FDA required, and all other additional information that the FDA requested
 25 over the three-year period of correspondence with BPV regarding this device, and finding
 26 that the G2® Filter was as safe and effective as, and therefore substantially equivalent to,
 27 the G2® Filter System – Femoral Delivery Kit and the G2® Filter System –
 28 Jugular/Subclavian Delivery Kit. Ex. A, Carr Decl. at ¶ 104.

Deny the referenced testing was “extensive.” Further deny that the FDA was requiring or mandating any action by Bard other than complying with the standard requirements for 510(k) submission, or that BPV intended the testing performed to be for any purpose other than establishing substantial equivalence under the 510(k) process. For example, in discussing the EVEREST study, Bard states in its 510(k) that the “goal of this investigation and related analysis was to generate valid scientific evidence in support of a finding of substantial equivalence for this device when used as a retrievable filter.” Bard SOF Ex. A at Ex. 102 at 51. Lastly, deny that any “special control” applicable to IVC filters under C.F.R. § 870.3375 was specific to Bard filters or specified any required testing to be performed. *See* Ex. 5 at 51:15-17; Ex. 11 at 108-109. Admit that the device was cleared by the FDA to be marketed based on its substantial equivalence to the predicate device, as with all 510(k) cleared devices.

V. G2® Express/G2®X Filter System

A. G2® Express Filter System – Femoral and Jugular/Subclavian Delivery Kits (K080668)

369. On March 7, 2008, BPV submitted a Special 510(k) for its G2® Express Filter System – Femoral and Jugular/Subclavian Delivery Kits. Ex. A, Carr Decl. at ¶ 105.

Admit.

370. Using the recently cleared G2® Filter System for removal indication (K073090) as a predicate device, BPV sought to gain approval for a filter with an electropolished snarable tip. Ex. A, Carr Decl. at ¶ 105.

Admit.

371. Other than the addition of the tip, no other changes to the filter were made. BPV also proposed minor changes to its femoral and jugular/subclavian delivery kits. Ex. A, Carr Decl. at ¶ 105.

Admit.

372. Included in the 510(k) submission were results from the *in-vitro* bench testing and *in-vivo* animal testing conducted by BPV on the subject device, including testing of, among other things, Filter Height, Filter Removal Force, Tensile Strength, Compressive Force, Cyclic Fatigue, Corrosion Resistance, Filter Tip Radiopacity, MRI Compatibility, Flushability, Delivery System Pushability, Delivery System Trackability, and Filter Centering. Ex. A, Carr Decl. at ¶ 105.

Admit that the 510(k) submission (Bard SOF Ex. A at Ex. 104) included “summaries” of tests allegedly performed. Deny that Bard provided the actual data setting forth results or supporting its conclusions. *Id.* Further deny that the testing performed was anything more than that required via the 510(k) process. Ex. 3 at 20.

373. BPV conducted a risk analysis, a Risk Assessment and Design Failure Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO 14971:2000, Medical Devices – Application of risk management to medical devices, to assure that risks posed by the design were acceptable. Ex. A, Carr Decl. at ¶ 105.

Deny. The referenced document, Bard SOF Ex. A at Ex. 104, states that the DFMEA was “performed in accordance with internal procedures based on ISO 14971:2000....” It is unclear whether the internal Bard standards wholesale adopted the referenced ISO standard. Further deny that the ISO referenced is a “special control” applicable to IVC filters under C.F.R. § 870.3375.

374. The design verification and validation were performed in conformance with FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular Filter 510(k) Submission;” FDA’s “510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1);” FDA’s “Use of International Standards Organizations ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;” BS EN 12006-3:1999 entitled, “Non-Active Surgical Implants – Particular Requirements for Cardiac and Vascular Implants – Part 3: Endovascular Devices;” FDA guidance document, Design Control Guidance for Medical Device Manufacturers, dated March 11, 1997; and the design control requirements under 21 CFR § 820.30. Ex. A, Carr Decl. at ¶ 105.

1 **Deny.** The referenced document section states the “verification and validation
2 of the design changes were performed with consideration to” the stated guidances,
3 not “in conformance with.” Bard SOF Ex. A at Ex. 99 at 20-21. Further deny that
4 BS EN 12006-3:1999 entitled “Non-Active Surgical Implants – Particular
5 Requirements for Cardiac and Vascular Implants – Part 3: Endovascular Devices”
6 is referenced in the portion of the 510(k) relied in for this representation. Bard SOF
7 Ex. A at Ex. 104 at 25, 180. Further deny that FDA guidance document, Design
8 Control Guidance for Medical Device Manufacturers, dated March 11, 1997, and the
9 design control requirements under 21 C.F.R. § 820.30 are “special controls”
10 specifically applicable to IVC filters under C.F.R. § 870.3375. Additionally,
11 “Guidance for Cardiovascular Intravascular Filter 510(k) Submission” clearly states
12 it “describes a means by which cardiovascular intravascular filter devices may
13 comply with the requirement of special controls for Class II devices.” It also states
14 that the “document is intended to provide guidance. It represents the Agency’s
15 current thinking on the above. It does not create or confer any rights for or on any
16 person and does not operate to bind FDA or the public. An alternative approach
17 may be used if such approach satisfies the requirements of the applicable statute,
18 regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-00034595). Lastly, deny that
19 “510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1),” or “Use of
20 International Standards Organizations ISO 10993 Biological Evaluation of Medical
21 Devices Part I: Evaluation and Testing” are specific to Bard IVC filters or
22 retrievable filters generally.

23 375. The submission also included reference to the extensive clinical results of
24 the EVEREST clinical study, which were applicable to the subject device because “there
25 were no design modifications to the filter or delivery systems that would affect the safety
26 of removability.” Ex. A, Carr Decl. at ¶ 105.

27 **Admit that the EVEREST study was referenced in the submission, and that**
28 **BPV included the represented quote in that submission. Deny that any results or**

1 data was included to support BPV's stated conclusion, and deny the clinical results
2 from the EVEREST study were "extensive," as it was limited to assessing "the safety
3 of removal of the Recovery G2 filter" (as opposed to long-term safety and efficacy,
4 etc.). Bard SOF Ex. A at Ex. 104 at 37.

5 376. Also included were results from biocompatibility and toxicity testing
6 conducted by BPV in conformance to ISO 10993-1:2003, Biological Evaluation of
7 Medical Devices – Part I: Evaluation and Testing. Ex. A, Carr Decl. at ¶ 105.

8 Deny to the extent the referenced biocompatibility testing was performed on
9 the predicate device, not the subject device. Bard SOF Ex. A at Ex. 104 at 39-41.
10 Further deny that Bard provided the actual data supporting its conclusions; instead,
11 the 510(k) simply states in summary fashion that testing was done and the device (or
12 predicate device) met the criteria. *Id.* Further deny that the ISO standard
13 referenced is specific to Bard IVC filters or retrievable filters generally.

14 377. Also included were results from packaging testing, sterilization testing, and
15 shelf-life testing. Ex. A, Carr Decl. at ¶ 105.

16 Deny, as the referenced testing was performed on the predicate device with
17 regard to packaging and shelf life, not the subject device. Bard SOF Ex. A at Ex. 104
18 at 37-39. Further deny that Bard provided any actual data setting forth results of
19 the testing performed on the subject or predicate device. *Id.* Admit that the
20 submission references sterilization testing performed.

21 378. Also included was proposed labeling for the G2® Express Filter in
22 conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 105.

23 Admit the 510(k) contained a copy of the proposed IFU for the subject device
24 and schematics of "pouches" containing the delivery system. Deny that 510(k)
25 contained a "labeling" which includes promotional materials, communications, etc.
26 Bard SOF Ex. A at Ex. 102. Further deny that 21 C.F.R. § 807.87 establishes any
27 "special control" applicable to IVC filters under CFR 870.3375; instead, that
28 regulation simply states the information required for a premarket notification.

1 379. Also included was a summary of the safety and effectiveness information
2 upon which a substantial equivalence determination could be based as required by the
3 Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 105.

4 **Admit.**

5 380. On April 8, 2008, the FDA sent a letter to BPV demanding additional
6 information to be able to complete the review of the device for substantial equivalence.
7 Ex. A, Carr Decl. at ¶ 106.

8 **Admit with clarification that the FDA was merely asking Bard to cure**
9 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
10 **action by Bard other than complying with the standard requirements for 510(k)**
11 **submission.**

12 381. The FDA prohibited BPV from marketing the device until it had provided
13 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 106.

14 **Admit with clarification that the FDA was merely asking Bard to cure**
15 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
16 **action by Bard other than complying with the standard requirements for 510(k)**
17 **submission.**

18 382. If BPV failed to respond within 30 days, the FDA would have treated this
19 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 106.

20 **Admit with clarification that the FDA was merely asking Bard to cure**
21 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
22 **action by Bard other than complying with the standard requirements for 510(k)**
23 **submission.**

24 383. The FDA inquired about the biocompatibility of the proposed filter, because
25 BPV's initial submission did not include certain biocompatibility testing. Ex. A, Carr
26 Decl. at ¶ 106.

27 **Admit with clarification that the FDA was merely asking Bard to cure**
28 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**

1 action by Bard other than complying with the standard requirements for 510(k)
 2 submission. In fact, the FDA left it to BPV whether to do the biocompatibility
 3 testing recommended for consideration: “Please provide full biocompatibility testing
 4 on the final device. Alternatively, provide additional justification for omission of any
 5 noted tests.” Bard SOF Ex. A at Ex. 105.

6 384. The FDA required BPV to provide full biocompatibility testing on the
 7 device or provide additional justification for omitting the testing. Ex. A, Carr Decl. at ¶
 8 106.

9 **Admit with clarification that the FDA was merely asking Bard to cure**
 10 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
 11 **action by Bard other than complying with the standard requirements for 510(k)**
 12 **submission. Deny that the FDA “required” BPV to do any testing. To the contrary,**
 13 **in discussing the biocompatibility tests to be performed, the FDA stated “CDHR**
 14 **recommends the following biocompatibility tests be considered.” Bard SOF Ex. A at**
 15 **Ex. 105.**

16 385. This full biocompatibility testing would require BPV to conduct testing for,
 17 among other things, cytotoxicity, sensitization, irritation or intracutaneous reactivity,
 18 acute systematic toxicity, subacute toxicity, material-mediated pyrogenicity,
 19 hemocompatibility, subchronic toxicity, implantation, chronic toxicity, genotoxicity, and
 20 carcinogenicity, in conformance with ISO 10993-1:2003, “Biological Evaluation of
 21 Medical Devices Part 1: Evaluation and Testing.” Ex. A, Carr Decl. at ¶ 106.

22 **Admit with clarification that the FDA was merely asking Bard to cure**
 23 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
 24 **action by Bard other than complying with the standard requirements for 510(k)**
 25 **submission. Deny that the FDA “required” BPV to do any testing. To the contrary,**
 26 **in discussing the biocompatibility tests to be performed, the FDA stated “CDHR**
 27 **recommends the following biocompatibility tests be considered.” Bard SOF Ex. A at**
 28 **Ex. 105. The FDA further left it to BPV whether to even do the biocompatibility**

1 **testing recommended for consideration: “Please provide full biocompatibility testing**
2 **on the final device. Alternatively, provide additional justification for omission of any**
3 **noted tests.” *Id.***

4 386. On May 5, 2008, in response to the FDA’s demand for additional
5 information, BPV requested an extension of time to respond. Ex. A, Carr Decl. at ¶ 107.

6 **Admit with clarification that the FDA was merely asking Bard to cure**
7 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
8 **action by Bard other than complying with the standard requirements for 510(k)**
9 **submission.**

10 387. On May 6, 2008, the FDA granted BPV’s request for an extension of time to
11 respond but indicated that if the additional information was not provided by that extended
12 date, the 510(k) would be considered withdrawn, pursuant to 21 C.F.R. § 807.87(l). Ex.
13 A, Carr Decl. at ¶ 107.

14 **Admit with clarification that the FDA was merely asking Bard to cure**
15 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
16 **action by Bard other than complying with the standard requirements for 510(k)**
17 **submission.**

18 388. On May 8, 2008, BPV submitted its response to the FDA’s demand for
19 additional information dated April 8, 2008. Ex. A, Carr Decl. at ¶ 108.

20 **Admit with clarification that the FDA was merely asking Bard to cure**
21 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
22 **action by Bard other than complying with the standard requirements for 510(k)**
23 **submission.**

24 389. BPV provided additional justification for omitting the testing in its original
25 submission, emphasizing that “full biocompatibility testing should be employed where
26 there is incongruence between the predicate and subject device base materials and where
27 processes differ between the devices as well.” Ex. A, Carr Decl. at ¶ 108.
28

1 **Admit with clarification that the FDA was merely asking Bard to cure**
2 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
3 **action by Bard other than complying with the standard requirements for 510(k)**
4 **submission.**

5 390. BPV reiterated that the starting material of the subject device did not change
6 from the predicate device, and emphasized that the only difference was the final
7 processing of the filter apex, noting that the new snarable tip was electropolished. Ex. A,
8 Carr Decl. at ¶ 108.

9 **Admit with clarification that the FDA was merely asking Bard to cure**
10 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
11 **action by Bard other than complying with the standard requirements for 510(k)**
12 **submission.**

13 391. Despite these explanations, BPV conducted additional biocompatibility
14 testing in response to the FDA's demands and provided detailed justification for omitting
15 other testing required by the FDA. Ex. A, Carr Decl. at ¶ 108.

16 **Deny the FDA was requiring or mandating any action by Bard other than**
17 **complying with the standard requirements for 510(k) submission. As discussed**
18 **above, the FDA only recommended certain biocompatibility tests be considered, and**
19 **allowed BPV the option to explain why testing was not needed as an alternative to**
20 **performing additional testing. Bard SOF Ex. A at Ex. 105. Admit the remainder of**
21 **the allegations with clarification. Bard, not the FDA, made the decision to move**
22 **forward with the additional biocompatibility testing, and it was Bard who**
23 **“determined the required tests [] to adequately evaluate the biocompatibility of the**
24 **subject device.” *Id.* at Ex. 108 (BPV-17-01-00130318).**

25 392. BPV conducted additional testing on cytotoxicity, sensitization, irritation,
26 system toxicity, hemocompatibility, 2-week implantation, and genotoxicity in conformance
27 with ISO 10993-1:2003, “Biological Evaluation of Medical Devices Part 1: Evaluation
28 and Testing.” Ex. A, Carr Decl. at ¶ 108.

1 **Deny the FDA was requiring or mandating any action by Bard other than**
2 **complying with the standard requirements for 510(k) submission. As discussed**
3 **above, the FDA only recommended certain biocompatibility tests be considered, and**
4 **allowed BPV the option to explain why testing was not needed as an alternative to**
5 **performing additional testing. Bard SOF Ex. A at Ex. 105. Further deny that ISO**
6 **standard referenced is specific to Bard filters or even IVC filters generally. Admit**
7 **the remainder of the allegations with clarification. Bard, not the FDA, made the**
8 **decision to move forward with the additional biocompatibility testing, and it was**
9 **Bard who “determined the required tests [] to adequately evaluate the**
10 **biocompatibility of the subject device.” Bard SOF Ex. A at Ex. 108 (BPV-17-01-**
11 **00130318).**

12 393. BPV did not complete additional testing on, and provided detailed
13 justification for omitting testing of, among other things, acute systemic toxicity, subacute
14 systemic toxicity, in vivo thrombogenicity, subchronic toxicity, chronic toxicity, and
15 carcinogenicity. Ex. A, Carr Decl. at ¶ 108.

16 **Admit with clarification that the FDA was merely asking Bard to cure**
17 **deficiencies in its initial 510(k), and that Bard, not the FDA, made the decision**
18 **whether to perform the referenced studies. Bard SOF Ex. A at Ex. 108. Deny the**
19 **FDA was requiring or mandating any action by Bard other than complying with the**
20 **standard requirements for 510(k) submission.**

21 394. On June 6, 2008, the FDA again sent a letter to BPV requiring additional
22 information to complete the review of the subject device. Ex. A, Carr Decl. at ¶ 109.

23 **Deny that the request sought additional information, as the letter again**
24 **requested the same information requested previously in its April 8, 2008 letter, and**
25 **again asked Bard to cure those deficiencies in its 510(k) submission. Bard SOF Ex.**
26 **A at Ex. 109. Further deny the FDA was requiring or mandating any action by Bard**
27 **other than complying with the standard requirements for 510(k) submission. Admit**
28

1 **the remaining allegations with clarification that the FDA was merely asking Bard to**
2 **cure deficiencies in its initial 510(k).**

3 395. The FDA stated that BPV did not adequately respond to the FDA's previous
4 demand for additional information. Ex. A, Carr Decl. at ¶ 109.

5 **Admit with clarification that the FDA was merely asking Bard to cure**
6 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
7 **action by Bard other than complying with the standard requirements for 510(k)**
8 **submission.**

9 396. The FDA required BPV to provide additional information supporting BPV's
10 justifications for declining to conduct the omitted biocompatibility testing. Ex. A, Carr
11 Decl. at ¶ 109.

12 **Admit with clarification that the FDA was merely asking Bard to cure**
13 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
14 **action by Bard other than complying with the standard requirements for 510(k)**
15 **submission.**

16 397. The FDA prohibited BPV from marketing the device until it had provided
17 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 109.

18 **Admit with clarification that the FDA was merely asking Bard to cure**
19 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
20 **action by Bard other than complying with the standard requirements for 510(k)**
21 **submission.**

22 398. If BPV failed to respond within 30 days, the FDA would have treated this
23 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 109.

24 **Admit with clarification that the FDA was merely asking Bard to cure**
25 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
26 **action by Bard other than complying with the standard requirements for 510(k)**
27 **submission.**

1 399. On June 25, 2008, before submitting its responses to the FDA's additional
2 requests, BPV held a meeting with the FDA to discuss the deficiencies noted by the FDA.
3 Ex. A, Carr Decl. at ¶ 110.

4 **Admit Bard SOF Ex. A at Ex. 110 states such a call occurred. Clarify that the**
5 **FDA was merely asking Bard to cure deficiencies in its initial 510(k). Deny the FDA**
6 **was requiring or mandating any action by Bard other than complying with the**
7 **standard requirements for 510(k) submission.**

8 400. The FDA reiterated its concern that BPV's responses did not provide
9 adequate additional information to address the FDA's concerns regarding biocompatibility
10 testing of surface contaminants and surface finish, and that such information must be
11 provided in BPV's response to the second additional information letter dated June 6,
12 2008. Ex. A, Carr Decl. at ¶ 110.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
14 **is reported to have said and what the conversation was reported to entail, as the**
15 **document referenced is simply a Bard internal memo summarizing a conversation.**
16 **Subject to said objection, deny that the FDA stated "such information must be**
17 **provided", as Bard SOF Ex. A at Ex. 110 states the FDA "believed BPV should**
18 **provide the information requested." Admit the document relied upon makes the**
19 **remaining representations.**

20 401. On June 26, 2008, BPV requested an additional extension of time to respond
21 to these new requests. Ex. A, Carr Decl. at ¶ 111.

22 **Deny that the request sought additional information, as the letter again**
23 **requested Bard cure the same deficiencies in its 510(k) submission previously**
24 **referenced in the FDA's April 8, 2008 letter, and again asked Bard to cure those**
25 **deficiencies in its 510(k) submission. Bard SOF Ex A at Ex.s 105, 109. Further deny**
26 **the FDA was requiring or mandating any action by Bard other than complying with**
27 **the standard requirements for 510(k) submission. Admit the remaining allegations**
28

1 **with clarification that the FDA was merely asking Bard to cure deficiencies in its**
2 **initial 510(k).**

3 402. On July 1, 2008, the FDA granted BPV's request for an extension of time to
4 respond, but indicated that if the additional information was not provided by that extended
5 date, the 510(k) would be considered withdrawn, pursuant to 21 C.F.R. § 807.87(l). Ex.
6 A, Carr Decl. at ¶ 111.

7 **Deny that the request sought additional information, as the letter again**
8 **requested Bard cure the same deficiencies in its 510(k) submission previously**
9 **referenced in the FDA's April 8, 2008 letter, and again asked Bard to cure those**
10 **deficiencies in its 510(k) submission. Bard SOF Ex A at Ex.s 105, 109. Further deny**
11 **the FDA was requiring or mandating any action by Bard other than complying with**
12 **the standard requirements for 510(k) submission. Admit the remaining allegations**
13 **with clarification that the FDA was merely asking Bard to cure deficiencies in its**
14 **initial 510(k).**

15 403. On July 2, 2008, BPV submitted an over 500-page response with the
16 additional information required by the FDA in the FDA letter dated June 6, 2008. Ex. A,
17 Carr Decl. at ¶ 112.

18 **Deny that the request sought additional information, as the letter again**
19 **requested Bard cure the same deficiencies in its 510(k) submission previously**
20 **referenced in the FDA's April 8, 2008 letter, and again asked Bard to cure those**
21 **deficiencies in its 510(k) submission. Bard SOF Ex A at Ex.s 105, 109. Further deny**
22 **the FDA was requiring or mandating any action by Bard other than complying with**
23 **the standard requirements for 510(k) submission. Admit the remaining allegations**
24 **with clarification that the FDA was merely asking Bard to cure deficiencies in its**
25 **initial 510(k).**

26 404. BPV answered each FDA question, provided additional information
27 supporting its justification for omitting certain biocompatibility tests, and provided
28

1 summaries and documentation of the biocompatibility testing it conducted in response to
 2 FDA's demand, including the protocols and testing reports. Ex. A, Carr Decl. at ¶ 112.

3 **Deny that the request sought additional information, as the letter again**
 4 **requested Bard cure the same deficiencies in its 510(k) submission previously**
 5 **referenced in the FDA's April 8, 2008 letter, and again asked Bard to cure those**
 6 **deficiencies in its 510(k) submission. Bard SOF Ex A at Ex.s 105, 109. Further deny**
 7 **the FDA was requiring or mandating any action by Bard other than complying with**
 8 **the standard requirements for 510(k) submission. Admit the remaining allegations**
 9 **with clarification that the FDA was merely asking Bard to cure deficiencies in its**
 10 **initial 510(k).**

11 405. On July 30, 2008, FDA cleared the G2® Express Filter for market, subject
 12 to the general controls and special controls of the FDCA, after reviewing the 510(k)
 13 submission and all additional information required by the FDA, and finding that the G2®
 14 Express Filter was as safe and effective as, and therefore substantially equivalent to, the
 15 G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits. Ex. A, Carr Decl. at
 16 ¶ 113.

17 **Admit.**

18 **B. G2®X Filter (K082305)**

19 406. On August 12, 2008, BPV submitted a Special 510(k) for its G2® Express
 20 Filter System – Femoral and Jugular/Subclavian Delivery Kits (subsequently known as
 21 G2®X), which included changes to the delivery system only. Ex. A, Carr Decl. at ¶ 114.

22 **Admit.**

23 407. In this submission, the filter remained unchanged from BPV's cleared G2®
 24 Express Filter System (K080668). Ex. A, Carr Decl. at ¶ 114.

25 **Admit.**

26 408. Included in the 510(k) submission were results from the *in-vitro* bench
 27 testing and *in-vivo* animal testing conducted by BPV on the subject device. Ex. A, Carr
 28 Decl. at ¶ 114.

1 **Admit that the 510(k) submission (Bard SOF Ex. A at Ex. 104) included**
 2 **“summaries” of tests allegedly performed. Deny that Bard provided the actual data**
 3 **setting forth results or supporting its conclusions. *Id.* Further deny that the testing**
 4 **performed was anything more than that required via the 510(k) process. Ex. 3 at 20.**

5 409. BPV conducted a risk analysis, a Risk Assessment and Design Failure
 6 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO
 7 14971:2000, Medical Devices – Application of risk management to medical devices, to
 8 assure that risks posed by the design were acceptable. Ex. A, Carr Decl. at ¶ 114.

9 **Deny. The referenced document, Bard SOF Ex. A at Ex. 115, states that the**
 10 **DFMEA was “performed in accordance with internal procedures based on ISO**
 11 **14971:2000....” It is unclear whether the internal Bard standards wholesale adopted**
 12 **the referenced ISO standard. Further deny that the ISO referenced is a “special**
 13 **control” applicable to IVC filters under C.F.R. § 870.3375.**

14 410. The design verification and validation were performed in conformance with
 15 FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular
 16 Filter 510(k) Submission;” FDA’s “510(k) Sterility Review Guidance and Revision of
 17 2/12/90 (K90-1);” FDA’s “Use of International Standards Organizations ISO 10993
 18 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;” FDA guidance
 19 document, Design Control Guidance for Medical Device Manufacturers, dated March 11,
 20 1997; and the design control requirements under 21 CFR § 820.30. Ex. A, Carr Decl. at
 21 ¶ 114.

22 **Deny. The referenced document section states the “verification and validation**
 23 **of the design changes were performed with consideration to” the stated guidances,**
 24 **not “in conformance with.” Bard SOF Ex. A at Ex. 115 at 32. Further deny that**
 25 **FDA guidance document, Design Control Guidance for Medical Device**
 26 **Manufacturers, dated March 11, 1997 and the design control requirements under 21**
 27 **C.F.R. § 820.30 are “special controls” specifically applicable to IVC filters under**
 28 **C.F.R. § 870.3375. Additionally, “Guidance for Cardiovascular Intravascular Filter**

1 **510(k) Submission” clearly states it “describes a means by which cardiovascular**
 2 **intravascular filter devices may comply with the requirement of special controls for**
 3 **Class II devices.” It also states that the “document is intended to provide guidance. It**
 4 **represents the Agency’s current thinking on the above. It does not create or confer**
 5 **any rights for or on any person and does not operate to bind FDA or the public. An**
 6 **alternative approach may be used if such approach satisfies the requirements of the**
 7 **applicable statute, regulations, or both.” Bard SOF Ex. F at 1 (BPV-17-01-**
 8 **00034595). Lastly, deny that “510(k) Sterility Review Guidance and Revision of**
 9 **2/12/90 (K90-1),” or “Use of International Standards Organizations ISO 10993**
 10 **Biological Evaluation of Medical Devices Part I: Evaluation and Testing” are**
 11 **specific to Bard IVC filters or retrievable filters generally.**

12 411. Also included in the submission were results from biocompatibility and
 13 toxicity testing conducted by BPV on cytotoxicity, sensitization, irritation/intracutaneous
 14 reactivity, acute systemic toxicity, pyrogenicity, and hemocompatibility, in conformance
 15 to ISO 10993-1:2003, Biological Evaluation of Medical Devices – Part I: Evaluation and
 16 Testing. Ex. A, Carr Decl. at ¶ 114.

17 **Deny to the extent the referenced biocompatibility testing was performed on**
 18 **the predicate device, not the subject device. Bard SOF Ex. A at Ex. 113 at 67-73.**
 19 **Further deny that Bard provided the actual data supporting its conclusions; instead,**
 20 **the 510(k) simply states in summary fashion that testing was done and the device (or**
 21 **predicate device) met the criteria. *Id.* Further deny that the ISO standard**
 22 **referenced is specific to Bard IVC filters or retrievable filters generally. Admit the**
 23 **remaining allegations with clarification that Bard was not taking any action outside**
 24 **of the normal 510(k) clearance process.**

25 412. Also included were results from packaging testing, sterilization testing, and
 26 shelf-life testing. Ex. A, Carr Decl. at ¶ 114.

27 **Admit that the 510(k) submission included “summaries” of a number of tests**
 28 **allegedly performed. Bard SOF Ex. A at Ex. 115 at 55-66. Deny that Bard provided**

1 **the actual data setting forth results or supporting its conclusions. *Id.* Further clarify**
2 **that Bard was not taking any action outside of the normal 510(k) clearance process.**

3 413. Also included was proposed labeling for the G2® Express Filter (G2®X) in
4 conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 114.

5 **Admit the 510(k) contained a copy of the proposed IFU for the subject device**
6 **and schematics of “pouches” containing the delivery system. Deny that 510(k)**
7 **contained a “labeling” which includes promotional materials, communications, etc.**
8 **Bard SOF Ex. A at Ex. 115. Further deny that 21 C.F.R. § 807.87 establishes any**
9 **“special control” applicable to IVC filters under C.F.R. § 870.3375; instead, that**
10 **regulation simply states the information required for a premarket notification.**

11 414. Also included was a summary of the safety and effectiveness information
12 upon which a substantial equivalence determination could be based as required by the
13 Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 114.

14 **Admit.**

15 415. On September 4, 2008, the FDA required BPV to provide additional
16 information before the FDA could complete its review of this submission for substantial
17 equivalence. Ex. A, Carr Decl. at ¶ 115.

18 **Admit that the FDA sent a letter requesting additional information, but deny**
19 **that this was in addition to information required as part of the 510(k) process. In**
20 **fact, the FDA asked Bard to respond to "the following deficiencies" the FDA noted.**

21 416. The FDA required BPV to provide the test reports for the *in vitro* testing
22 conducted to validate the device modifications (Question 1). Ex. A, Carr Decl. at ¶ 115.

23 **Deny. The FDA requested that Bard provide an explanation of certain issues**
24 **concerning the testing it performed or, as an alternative, provide the test reports for**
25 **that testing. Bard SOF Ex. A at Ex. 116. There was no mandate of any kind from**
26 **the FDA on provision of the referenced test results. *Id.***

1 417. The FDA required BPV to provide information regarding whether BPV was
2 experiencing issues with oxidation and/or stability of the material in the predicate device
3 (Question 2). Ex. A, Carr Decl. at ¶ 115.

4 **Admit with clarification that the FDA was merely asking Bard to cure**
5 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
6 **action by Bard other than complying with the standard requirements for 510(k)**
7 **submission.**

8 418. The FDA required BPV to provide summaries of the biocompatibility
9 testing conducted on the proposed device by completing a biocompatibility testing results
10 form provided by the FDA (Question 3). Ex. A, Carr Decl. at ¶ 115.

11 **Admit with clarification that the FDA was merely asking Bard to cure**
12 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
13 **action by Bard other than complying with the standard requirements for 510(k)**
14 **submission.**

15 419. On September 8, 2008, the FDA sent BPV a letter informing BPV that the
16 FDA was putting the 510(k) submission on hold pending BPV's responses to the FDA's
17 requests. Ex. A, Carr Decl. at ¶ 116.

18 **Admit with clarification that the FDA was merely asking Bard to cure**
19 **deficiencies in its initial 510(k). The FDA specifically stated: "The deficiencies**
20 **identified represent the issues we believe need to be resolved before our review of**
21 **your 510(k) submission can be successfully completed. In developing the**
22 **deficiencies, we carefully considered the statutory criteria ... for determining**
23 **substantial equivalence of your device." Bard SOF Ex. A at Ex. 117. Deny the FDA**
24 **was requiring or mandating any action by Bard other than complying with the**
25 **standard requirements for 510(k) submission.**

26 420. If BPV failed to respond within 30 days, the FDA would have treated this
27 510(k) submission as withdrawn under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 116.

1 **Admit with clarification that the FDA was merely asking Bard to cure**
2 **deficiencies in its initial 510(k). The FDA specifically stated: “The deficiencies**
3 **identified represent the issues we believe need to be resolved before our review of**
4 **your 510(k) submission can be successfully completed. In developing the**
5 **deficiencies, we carefully considered the statutory criteria ... for determining**
6 **substantial equivalence of your device.” Bard SOF Ex. A at Ex. 117. Deny the FDA**
7 **was requiring or mandating any action by Bard other than complying with the**
8 **standard requirements for 510(k) submission.**

9 421. On September 29, 2008, BPV submitted the additional information required
10 by the FDA in its September 4, 2008 email. Ex. A, Carr Decl. at ¶ 117.

11 **Admit with clarification that the FDA was merely asking Bard to cure**
12 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
13 **action by Bard other than complying with the standard requirements for 510(k)**
14 **submission.**

15 422. In response to FDA’s demand (Question 1), BPV provided the FDA with a
16 summary of its *in vitro* testing and the test reports to validate its proposed modifications.
17 Ex. A, Carr Decl. at ¶ 117.

18 **Admit that the response included “summaries” of a number of tests allegedly**
19 **performed. Bard SOF Ex. A at Ex. 118. Deny that Bard provided the actual data**
20 **setting forth results or supporting its conclusions. *Id.* Further deny the FDA was**
21 **requiring or mandating any action by Bard other than complying with the standard**
22 **requirements for 510(k) submission. Admit remaining allegations with clarification**
23 **that the FDA was merely asking Bard to cure deficiencies in its initial 510(k).**

24 423. In response to FDA’s demand (Question 2), BPV provided the FDA with an
25 explanation regarding the isolated event of issues with oxidation and/or stability of the
26 material in the predicate device that BPV experienced, as well as BPV’s investigation of
27 the probable root causes of the failure mode and the immediate corrective actions that
28

1 BPV implemented, which appeared to resolve the failure mode (no reported complaints
2 since action taken). Ex. A, Carr Decl. at ¶ 117.

3 **Admit with clarification that the “no reported complaints since action taken”**
4 **related only to the specific failure mode at issue – i.e. degraded radiopaque tips on**
5 **the introducer sheath – and that the FDA was merely asking Bard to cure**
6 **deficiencies in its initial 510(k). Bard SOF Ex. A at Ex. 118. Deny the FDA was**
7 **requiring or mandating any action by Bard other than complying with the standard**
8 **requirements for 510(k) submission.**

9 424. In response to FDA’s demand (Question 3), BPV provided the FDA with
10 the completed Biocompatibility Test Results Forms that summarized the biocompatibility
11 testing conducted on the subject device. Ex. A, Carr Decl. at ¶ 117.

12 **Admit with clarification that the FDA was merely asking Bard to cure**
13 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
14 **action by Bard other than complying with the standard requirements for 510(k)**
15 **submission.**

16 425. On October 31, 2008, the FDA cleared the G2®X Filter for market, subject
17 to the general controls and special controls of the FDCA, after reviewing the 510(k)
18 submission and all additional information required by the FDA, and finding the G2®X
19 Filter as safe and effective as, and therefore substantially equivalent to, the G2® Express
20 Filter System – Femoral and Jugular/Subclavian Delivery Kits. Ex. A, Carr Decl. at ¶
21 118.

22 **Deny the FDA required any “additional information” from Bard; instead, it**
23 **was asking Bard to cure deficiencies in its initial 510(k). Further deny FDA required**
24 **or mandated any action by Bard other than complying with the standard**
25 **requirements for 510(k) submission. Admit the remaining allegations.**

26 **VI. ECLIPSE™ Filter System**

27 **A. ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery**
28 **Kits (K093659)**

1 426. On August 14, 2009, BPV met with FDA to discuss its upcoming filter
2 project which made minor process changes to the surface finish of the G2®X Filter. Ex.
3 A, Carr Decl. at ¶ 119.

4 **Objection. This statement contains inadmissible hearsay as to what the FDA**
5 **is reported to have said and what the conversation was reported to entail, as the**
6 **document referenced is simply a Bard internal memo summarizing a conversation.**
7 **Subject to said objection, deny the primary purpose of the meeting was to discuss the**
8 **changes to the G2X surface finish, but admit that the document relied upon so states.**

9 427. The purpose of the meeting was for BPV to obtain FDA guidance on the
10 proper regulatory path for this project. Ex. A, Carr Decl. at ¶ 119.

11 **Admit.**

12 428. The modifications would not result in any dimensional, physical, or
13 performance changes to the filter or the delivery system and the risk assessment that BPV
14 conducted identified “no new issues of safety and effectiveness.” Ex. A, Carr Decl. at ¶
15 119.

16 **Objection. This statement contains inadmissible hearsay as to what the FDA**
17 **is reported to have said and what the conversation was reported to entail, as the**
18 **document referenced is simply a Bard internal memo summarizing a conversation.**
19 **Subject to said objection, admit that document relied upon makes this**
20 **representation.**

21 429. Accordingly, BPV followed FDA’s guidance document “Deciding When to
22 Submit a 510(k) for a Change to an Existing Device,” which included a decision tree that
23 BPV followed and which determined that this minor modification should not require a
24 new 510(k). Ex. A, Carr Decl. at ¶ 119.

25 **Deny, as the referenced guidance is not mentioned in the document relied**
26 **upon in this SOF.**

1 430. BPV sought FDA's input because BPV believed "in an effort to keep FDA
2 informed of this change, a special 510(k) might be more appropriate." Ex. A, Carr Decl.
3 at ¶ 119.

4 **Objection. This statement contains inadmissible hearsay as to what the FDA**
5 **is reported to have said and what the conversation was reported to entail, as the**
6 **document referenced is simply a Bard internal memo summarizing a conversation.**
7 **Subject to said objection, admit that the document relied upon makes this**
8 **representation.**

9 431. FDA and BPV discussed the minor modification and FDA indicated that the
10 decision of whether to file a 510(k) or not to file in this case "was more of a decision for
11 the business," but that FDA would confirm with FDA compliance department. Ex. A,
12 Carr Decl. at ¶ 119.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
14 **is reported to have said and what the conversation was reported to entail, as the**
15 **document referenced is simply a Bard internal memo summarizing a conversation.**
16 **Subject to said objection, admit that the document relied upon makes this**
17 **representation.**

18 432. On November 23, 2009, BPV decided to submit a formal Special 510(k) for
19 its ECLIPSE Filter System – Femoral and Jugular/Subclavian Delivery Kits. Ex. A, Carr
20 Decl. at ¶ 120.

21 **Admit.**

22 433. The primary change from the predicate device, the G2®X Filter System –
23 Femoral and Jugular/Subclavian Delivery System (K082305), was an improvement in the
24 surface finish of the filter wire by electropolishing the wire prior to forming the filter. Ex.
25 A, Carr Decl. at ¶ 120.

26 **Admit this is the primary change to the device stated in the 510(k). Deny that**
27 **the change ultimately resulted in an "improvement in the surface finish."**
28

1 434. Included in the 510(k) submission were results from the *in-vitro* bench
 2 testing conducted by BPV on the subject device, including corrosion resistance testing,
 3 cyclic fatigue testing, and arm fatigue testing. Ex. A, Carr Decl. at ¶ 120.

4 **Admit that the 510(k) submission (Bard SOF Ex. A at Ex. 121) included**
 5 **“summaries” of tests allegedly performed. Deny that Bard provided the actual data**
 6 **setting forth results or supporting its conclusions. *Id.* Further deny that the testing**
 7 **performed was anything more than that required via the 510(k) process. Ex. 3 at 20.**

8 435. BPV conducted a risk analysis, a Risk Assessment and Design Failure
 9 Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO
 10 14971:2000, Medical Devices – Application of Risk Management to Medical Devices,” to
 11 assure that risks posed by the design were acceptable. Ex. A, Carr Decl. at ¶ 120.

12 **Deny. The referenced document, Bard SOF Ex. A at Ex. 121, states that the**
 13 **DFMEA was “performed in accordance with internal procedures based on ISO**
 14 **14971:2000....” It is unclear whether the internal Bard standards wholesale adopted**
 15 **the referenced ISO standard. Further deny that the ISO referenced is a “special**
 16 **control” applicable to IVC filters under C.F.R. § 870.3375.**

17 436. The design verification and validation were performed in conformance with
 18 FDA Special Controls guidance document, “Guidance for Cardiovascular Intravascular
 19 Filter 510(k) Submission;” FDA’s “510(k) Sterility Review Guidance and Revision of
 20 2/12/90 (K90-1);” FDA’s “Use of International Standards Organizations ISO 10993
 21 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;” FDA guidance
 22 document, Design Control Guidance for Medical Device Manufacturers, dated March 11,
 23 1997; ASTM F2129-06 Stand Test Method for Conducting Cyclic Potentiodynamic
 24 Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant
 25 Devices; and the design control requirements under 21 CFR § 820.30. Ex. A, Carr Decl.
 26 at ¶ 120.

27 **Deny. The referenced document section states the “verification and validation**
 28 **of the design changes were performed with consideration to” the stated guidances,**

1 not “in conformance with.” Bard SOF Ex. A at Ex. 121 at 35. Further deny that
 2 FDA guidance document, Design Control Guidance for Medical Device
 3 Manufacturers, dated March 11, 1997, ASTM F2129-06 Stand Test Method for
 4 Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the
 5 Corrosion Susceptibility of Small Implant Devices, and the design control
 6 requirements under 21 C.F.R. § 820.30 are “special controls” specifically applicable
 7 to IVC filters under CFR 870.3375. Additionally, “Guidance for Cardiovascular
 8 Intravascular Filter 510(k) Submission” clearly states it “describes a means by which
 9 cardiovascular intravascular filter devices may comply with the requirement of
 10 special controls for Class II devices.” It also states that the “document is intended to
 11 provide guidance. It represents the Agency’s current thinking on the above. It does
 12 not create or confer any rights for or on any person and does not operate to bind
 13 FDA or the public. An alternative approach may be used if such approach satisfies
 14 the requirements of the applicable statute, regulations, or both.” Bard SOF Ex. F at
 15 1 (BPV-17-01-00034595). Lastly, deny that “510(k) Sterility Review Guidance and
 16 Revision of 2/12/90 (K90-1),” or “Use of International Standards Organizations ISO
 17 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing” are
 18 specific to Bard IVC filters or retrievable filters generally.

19 437. Also included in the submission were results from biocompatibility testing
 20 conducted by BPV in conformance to ISO 10993-1:2003, Biological Evaluation of
 21 Medical Devices – Part I: Evaluation and Testing. Ex. A, Carr Decl. at ¶ 120.

22 **Deny.** The referenced biocompatibility testing was performed on the predicate
 23 device, not the subject device. Bard SOF Ex. A at Ex. 121 at 21-24. Further deny
 24 that Bard provided the actual data supporting its conclusions; instead, the 510(k)
 25 simply states in summary fashion that testing was done and the predicate device met
 26 the criteria. *Id.* Further deny that the ISO standard referenced is specific to Bard
 27 IVC filters or retrievable filters generally.

1 438. Also included were results from packaging testing, sterilization testing, and
2 shelf-life testing. Ex. A, Carr Decl. at ¶ 120.

3 **Deny. No testing was performed or the testing was performed on the**
4 **predicate device. Bard SOF Ex. A at Ex. 121 at 20-24. Further deny that Bard**
5 **provided the actual data supporting its conclusions; instead, the 510(k) simply states**
6 **in summary fashion that testing was done and the predicate device met the criteria.**
7 ***Id.***

8 439. Also included was proposed labeling for the Eclipse™ Filter in
9 conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 120.

10 **Admit the 510(k) contained a copy of the proposed IFU for the subject device**
11 **and schematics of “pouches” containing the delivery system. Deny that 510(k)**
12 **contained a “labeling” which includes promotional materials, communications, etc.**
13 **Bard SOF Ex. A at Ex. 102. Further deny that 21 C.F.R. § 807.87 establishes any**
14 **“special control” applicable to IVC filters under C.F.R. § 870.3375; instead, that**
15 **regulation simply states the information required for a premarket notification.**

16 440. Also included was a summary of the safety and effectiveness information
17 upon which a substantial equivalence determination could be based as required by the
18 Safe Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 120.

19 **Admit.**

20 441. On December 15, 2009, the FDA reviewed the submission but demanded
21 additional information before the FDA could complete its review of this submission for
22 substantial equivalence. Ex. A, Carr Decl. at ¶ 121.

23 **Admit with clarification that the FDA was merely asking Bard to cure**
24 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
25 **action by Bard other than complying with the standard requirements for 510(k)**
26 **submission.**

1 442. The FDA required BPV to conduct additional testing on the subject device
2 for radial force testing, migration/clot trapping testing, and tensile strength testing or
3 provide justification for why these tests were not necessary. Ex. A, Carr Decl. at ¶ 121.

4 **Admit with clarification that the FDA was merely asking Bard to cure**
5 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
6 **action by Bard other than complying with the standard requirements for 510(k)**
7 **submission. In fact, the FDA left it to BPV whether to do the testing recommended**
8 **or “provide a justification for why each of those tests is necessary. Bard SOF Ex. A**
9 **at Ex. 122.**

10 443. The FDA prohibited BPV from marketing the device until it had provided
11 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 121.

12 **Admit with clarification that the FDA was merely asking Bard to cure**
13 **deficiencies in its initial 510(k). The FDA specifically stated: “The deficiency**
14 **identified above represents the issue we believe needs to be resolved before our**
15 **review of your 510(k) submission can be successfully completed. In developing the**
16 **deficiency, we carefully considered the statutory criteria ... for determining**
17 **substantial equivalence of your device.” Bard SOF Ex. A at Ex. 122. Deny the FDA**
18 **was requiring or mandating any action by Bard other than complying with the**
19 **standard requirements for 510(k) submission.**

20 444. If BPV failed to respond within 30 days, the FDA would have treated this
21 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 121.

22 **Admit with clarification that the FDA was merely asking Bard to cure**
23 **deficiencies in its initial 510(k). The FDA specifically stated: “The deficiency**
24 **identified above represents the issue we believe needs to be resolved before our**
25 **review of your 510(k) submission can be successfully completed. In developing the**
26 **deficiency, we carefully considered the statutory criteria ... for determining**
27 **substantial equivalence of your device.” Bard SOF Ex. A at Ex. 122. Deny the FDA**
28

1 **was requiring or mandating any action by Bard other than complying with the**
2 **standard requirements for 510(k) submission.**

3 445. On December 17, 2009, BPV responded to FDA's request and provided the
4 additional information required by FDA in its December 15, 2009 letter. Ex. A, Carr
5 Decl. at ¶ 122.

6 **Admit with clarification that the FDA was merely asking Bard to cure**
7 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
8 **action by Bard other than complying with the standard requirements for 510(k)**
9 **submission.**

10 446. BPV responded with the justification for why the testing was not included in
11 the original submission, but, nevertheless, BPV conducted the additional testing required
12 by the FDA and provided summary results for the radial strength testing, migration/clot
13 trapping testing, and tensile strength testing. Ex. A, Carr Decl. at ¶ 122.

14 **Admit with clarification that the FDA was merely asking Bard to cure**
15 **deficiencies in its initial 510(k). The FDA specifically stated: "The deficiency**
16 **identified above represents the issue we believe needs to be resolved before our**
17 **review of your 510(k) submission can be successfully completed. In developing the**
18 **deficiency, we carefully considered the statutory criteria ... for determining**
19 **substantial equivalence of your device." Bard SOF Ex. A at Ex. 122. Deny the FDA**
20 **was requiring or mandating any action by Bard other than complying with the**
21 **standard requirements for 510(k) submission. Bard, not the FDA, made the decision**
22 **to move forward with the additional testing. *Id.* at Ex.s 122, 123.**

23 447. On January 14, 2010, the FDA cleared the EclipseTM Filter, subject to
24 FDCA general and special controls, after reviewing the submission and the additional
25 testing information that FDA required, and finding the EclipseTM Filter as safe and
26 effective as, and therefore substantially equivalent to, the G2®X Filter. Ex. A, Carr Decl.
27 at ¶ 123.

28 **Admit.**

1 448. BPV later made subsequent changes to the device labeling, developing a
2 patient brochure and implant card to accompany the Eclipse™ Filter. Ex. A, Carr Decl. at
3 ¶ 124.

4 **Admit.**

5 449. Again, BPV followed FDA's guidance document "Deciding When to
6 Submit a 510(k) for a Change to an Existing Device," which included a decision tree that
7 BPV followed and which determined that the changes did not require a 510(k). Ex. A,
8 Carr Decl. at ¶ 124.

9 **Admit in part, deny in part. Admit that the submission states BPV**
10 **"consulted" the guidance and "the described changes do not require premarket**
11 **notification," but deny that veracity of the statement has been confirmed.**

12 450. BPV sought FDA's review and input on the content of the patient brochure
13 and implant card. Ex. A, Carr Decl. at ¶ 124.

14 **Admit.**

15 451. On March 18, 2010, BPV and FDA had a telephone conference to discuss
16 BPV's proposed changes to the labeling. Ex. A, Carr Decl. at ¶ 125.

17 **Objection. This statement contains inadmissible hearsay as to what the FDA**
18 **is reported to have said and what the conversation was reported to entail. Subject to**
19 **said objection, admit that Bard contacted the FDA via telephone.**

20 452. FDA indicated that the patient brochure and implant card could not be
21 reviewed outside of a 510(k) submission, so BPV agreed to provide the labeling to the
22 FDA via a Special 510(k). Ex. A, Carr Decl. at ¶ 125.

23 **Objection. This statement contains inadmissible hearsay as to what the FDA**
24 **is reported to have said and what the conversation was reported to entail. Subject to**
25 **said objection, admit that the document relied upon makes this representation.**

26 453. On May 20, 2010, BPV filed the Special 510(k) for the Eclipse™ Filter
27 seeking clearance of the revised device labeling that added a patient brochure and implant
28

card, as well as a “Does not Contain Latex” symbol and corresponding text to the label.
Ex. A, Carr Decl. at ¶ 126.

Admit.

454. Because no changes were made to the Eclipse™ Filter or the delivery systems previously cleared by the FDA on January 14, 2010, BPV did not need to re-conduct the battery of testing that the FDA already reviewed when it cleared the device.
Ex. A, Carr Decl. at ¶ 126.

Objection. This statement contains inadmissible hearsay as to what the FDA is reported to have said and what the conversation was reported to entail. Subject to said objection, admit in part, deny in part. Admit that Bard made no changes to the Eclipse Filter or delivery system. Deny that deny the veracity of the statement has been confirmed and that the FDA reasoned that Bard did not need to conduct testing on Eclipse because they “had already reviewed” it.

455. BPV conducted a risk analysis, a Risk Assessment and Design Failure Modes and Effects Analysis (“DFMEA”) for the device, in accordance with ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices,” to assure that risks posed by the design were acceptable, which only identified packaging testing, sterilization testing, and shelf-life testing as necessary. Ex. A, Carr Decl. at ¶ 127.

Admit in part, deny in part or admit with clarification. Admit that Bard states in its submission it performed DFMEA. Deny that the results assured the risk posed by the device was acceptable or that that was the only three tests were necessary.

456. Included in the submission were results from the packaging testing, sterilization testing, and shelf-life testing that BPV conducted on the device. Ex. A, Carr Decl. at ¶ 127.

Admit in part, deny in part. Admit packaging testing was performed. Deny sterilization and shelf-life testing were conducted and included in the submission. Instead, the submission states the contrary. The sterilization testing “is identical to

1 the predicate” and “will be routinely performed”; and for shelf-life testing, the
2 submission states “there was no difference between predicate and subject devices
3 that may potentially impact shelf-life; therefore the subject device, the Eclipse, will
4 have a three year shelf-life identical to the predicate device.” See Bard SOF Ex. A at
5 Ex. 125 at 20-22.

6 457. Also included were results from the chemical testing that BPV conducted on
7 the device to confirm that the device did not contain latex, including Fourier transform
8 infrared spectroscopy, and gas chromatography mass spectroscopy, as well as provided
9 the test data and reports to FDA. Ex. A, Carr Decl. at ¶ 127.

10 **Admit.**

11 458. Also included was proposed revised labeling for the EclipseTM Filter in
12 conformance with 21 CFR § 807.87(e). Ex. A, Carr Decl. at ¶ 127.

13 **Admit Bard included labeling language in their submission in conformity with**
14 **the 510(k) clearance process.**

15 459. Also included was a summary of the safety and effectiveness information
16 upon which substantial equivalence determination would be based as required by the Safe
17 Medical Devices Act of 1990, and 21 CFR § 807.92. Ex. A, Carr Decl. at ¶ 127.

18 **Admit in part, deny in part. Admit that a 510(k) summary is required in the**
19 **submission. Deny that the 510(k) summary is an independent determination of the**
20 **safety and effectiveness of the device.**

21 460. On June 18, 2010, the FDA reviewed the submission but required BPV to
22 provide additional information before the FDA could complete its review of the
23 submission for substantial equivalence. Ex. A, Carr Decl. at ¶ 128.

24 **Admit with clarification that the FDA was merely asking Bard to cure**
25 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
26 **action by Bard other than complying with the standard requirements for 510(k)**
27 **submission. As stated in the letter, FDA was seeking “adequate information**
28 **described and required by to 21 CFR 807.87(l).”**

1 461. The FDA prohibited BPV from marketing the device until it had provided
2 the additional information under 21 CFR § 807.87(l). Ex. A, Carr Decl. at ¶ 128.

3 **Admit with clarification that the FDA was merely asking Bard to cure**
4 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
5 **action by Bard other than complying with the standard requirements for 510(k)**
6 **submission. As stated in the letter, FDA was seeking “adequate information**
7 **described and required by to 21 CFR 807.87(l).”**

8 462. If BPV failed to respond within 30 days, the FDA would have treated this
9 510(k) submission as withdrawn. Ex. A, Carr Decl. at ¶ 128.

10 **Admit.**

11 463. FDA required BPV to revise the labeling of the Eclipse™ Filter to remove
12 the statement “The Eclipse Vena Cava Filter does not have a time in which it must be
13 removed” in the “When can the filter be removed?” section of the labeling (Question 1).
14 Ex. A, Carr Decl. at ¶ 128.

15 **Admit in part, deny in part. Admit that the quoted statement is accurate.**
16 **Deny the FDA was requiring or mandating any action by Bard other than complying**
17 **with the standard requirements for 510(k) submission. This statement**
18 **mischaracterizes FDA’s statements to imply that the statement in the letter imposed**
19 **mandatory requirements on Bard. In fact, the FDA suggested this update because**
20 **Bard’s data (58 patients with a mean retrieval time of 140 days) was “not sufficient**
21 **to substantiate the statement that the filter does not have a time limit for removal.**
22 **Please provide additional data to support this language in your brochure.**
23 ***Alternatively, please remove this section from the patient brochure.” (emphasis added).***
24 **Further, Dr. Kessler stated at his July 31, 2017, deposition that labeling revisions**
25 **and changes are a negotiation between the FDA and a manufacturer. See Ex. 11 at**
26 **92:1-4.**

27 464. FDA was concerned that the clinical data BPV provided in the labeling was
28 not sufficient enough to support this statement. Ex. A, Carr Decl. at ¶ 128.

1 **Admit. The FDA stated the labeling “is not sufficient to substantiate the**
 2 **statement that the filter does not have a time limit for removal.”**

3 465. The FDA also directed BPV to revise the 510(k) submission to include
 4 additional information in the 510(k) summary pursuant to 21 C.F.R. § 807.92 (Question
 5 2). Ex. A, Carr Decl. at ¶ 128.

6 **Admit in part, deny in part. Admit that the FDA sent a letter seeking**
 7 **supplementary information due to deficiencies in Bard’s submission. Deny the FDA**
 8 **was requiring or mandating any action by Bard other than complying with the**
 9 **standard requirements for 510(k) submission. As stated in the letter, FDA was**
 10 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

11 466. The FDA further directed BPV to revise the 510(k) submission to remove
 12 “Trade Secret/Confidential” from the footer of the 510(k) summary (Question 2) and the
 13 Indication for Use page (Question 3). Ex. A, Carr Decl. at ¶ 128.

14 **Admit with clarification that the FDA was merely asking Bard to cure**
 15 **deficiencies in its initial 510(k). Deny the FDA was requiring or mandating any**
 16 **action by Bard other than complying with the standard requirements for 510(k)**
 17 **submission.**

18 467. On June 21, 2010, BPV responded to FDA’s demands for additional
 19 information and revised labeling. Ex. A, Carr Decl. at ¶ 129.

20 **Objection; Hearsay. Mischaracterization of “demand.”**

21 **Admit in part, deny in part. Admit that the FDA sent a letter requesting**
 22 **additional information, but deny that this was *in addition* to information required as**
 23 **part of the 510(k) clearance process. FDA was seeking “adequate information**
 24 **described and required by to 21 CFR 807.87(l).” Labeling revisions and changes are**
 25 **negotiated between the FDA and a manufacturer, not demanded. *See* Ex. 11 at 92:1-**
 26 **4.**

1 468. In response to FDA’s demand (Question 1), BPV revised the labeling for the
 2 Eclipse™ Filter and removed the section entitled “When can the filter be removed?” and
 3 provided the revised version to the FDA. Ex. A, Carr Decl. at ¶ 129.

4 **Objection, statement is based upon inadmissible hearsay and lacks**
 5 **foundation. Furthermore, statement mischaracterizes the letter as a “demand.”**
 6 **Subject to said objections, admit in part and deny on part. Admit that Bard revised**
 7 **labeling due to deficiencies addressed in FDA’s June 18, 2010, letter as stated on**
 8 **page 3, “this submission responds to FDA deficiency letter for the Eclipse Filter**
 9 **System.” Deny that the FDA demanded this revision. Labeling revisions and changes**
 10 **are negotiated between the FDA and a manufacturer, not demanded. See Ex. 11 at**
 11 **92:1-4.**

12 469. In response to FDA’s demand (Question 2), BPV revised the 510(k)
 13 Summary included with the original 510(k) submission and provided the revised version
 14 to the FDA. Ex. A, Carr Decl. at ¶ 129.

15 **Objection, statement is based upon inadmissible hearsay and lacks**
 16 **foundation. Furthermore, statement mischaracterizes the letter as a “demand.”**
 17 **Subject to said objections, admit in part and deny on part. Admit that Bard revised**
 18 **the summary 510(k) section due to deficiencies addressed in the FDA’s June 18, 2010**
 19 **letter, but deny that the FDA “demanded” the revision or that it was *in addition to***
 20 **information required as part of the 510(k) clearance process.**

21 470. In response to FDA’s demand (Question 3), BPV revised the Indications for
 22 Use page included with the original 510(k) submission and provided the revised version to
 23 the FDA. Ex. A, Carr Decl. at ¶ 129.

24 **Objection, statement is based upon inadmissible hearsay and lacks**
 25 **foundation. Furthermore, statement mischaracterizes the letter as a “demand.”**
 26 **Subject to said objections, admit in part and deny on part. Admit that Bard revised**
 27 **the Indications for Use page due to deficiencies addressed in the FDA’s June 18, 2010**
 28

1 **letter, but deny that the FDA “demanded” the revision or that it was *in addition to***
 2 **information required as part of the 510(k) clearance process.**

3 471. On June 25, 2010, the FDA cleared the revised labeling for the Eclipse™
 4 Filter, finding it as safe and effective as, and therefore substantially equivalent to, the
 5 Eclipse™ Filter, subject to the general controls and special controls of the FDCA. FDA
 6 reviewed the revised submission and the revised labeling. Ex. A, Carr Decl. at ¶ 130.

7 **Admit in part, deny in part. Admit cleared for marketing on October 31,**
 8 **2008. Deny that the FDA found the device "safe and effective as" the G2. A**
 9 **determination by the FDA in the 510(k) process that a device is substantially**
 10 **equivalent to a predicate device *is not a finding that the device is safe and effective for***
 11 ***its intended conditions of use. See Ex. 3 at 8. Deny that the FDA letter addressed or***
 12 **mentions specific special controls for IVC filters. Further, labeling revisions and**
 13 **changes are negotiated between the FDA and a manufacturer. See Ex. 11 at 92:1-4.**

14 **VII. Meridian® Filter:**

15 472. As early as August 14, 2009, BPV began discussing with the FDA BPV's
 16 plans to develop the Meridian® Filter (more than two years before FDA cleared the
 17 device). Ex. B, Van Vleet Decl. at ¶ 10.

18 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 19 **is reported to have said and what the conversation was reported to entail, and lacks**
 20 **foundation. Subject to these objections, admit that the relied upon document**
 21 **references an August 14, 2009, meeting between Bard personnel and FDA**
 22 **representative Angela Smith, and that the memo of the meeting contains a passing**
 23 **reference to a “laser-cut filter with caudal anchors.” The statements that this is a**
 24 **reference to the Meridian filter or that this constituted a “discussion with FDA” of**
 25 **Bard's plans to develop the Meridian filter are unsupported by any exhibit and are**
 26 **denied. Instead this document discussed the G2 Platinum Project.**

1 473. The Meridian® Filter was to be BPV's next generation retrievable IVC
2 filter. The design goal for the Meridian® Filter was to improve the device's resistance to
3 caudal movement/migration. Ex. B, Van Vleet Decl. at ¶ 10.

4 **Deny. This document does not support this statement; it neither makes**
5 **reference to the Meridian filter nor sets forth design goals for this filter.**

6 474. In BPV's discussions with FDA, BPV described the project as one "based
7 on the existing filter platform [that] consisted of adding caudal anchors to the Filter."
8 This project eventually became the Meridian® Filter. Ex. B, Van Vleet Decl. at ¶ 10.

9 **Objection. This statement contains inadmissible hearsay as to what the FDA**
10 **is reported to have said and what the conversation was reported to entail. Subject to**
11 **this objection, admit in part, deny in part. Admit that Bard's meeting minutes**
12 **include the quoted statement. Deny that this statement is relates to the Meridian**
13 **filter or the project that eventually became the Meridian filter.**

14 475. On November 17, 2009, to ensure that the company was satisfying FDA's
15 requirements regarding animal testing for the Meridian® Filter, BPV asked FDA if the
16 agency would be willing to review BPV's proposed animal study protocol. Ex. B, Van
17 Vleet Decl. at ¶ 11.

18 **Objection. This statement contains inadmissible hearsay as to what the**
19 **conversation was reported to entail. Subject to this objection, deny that this**
20 **document references the Meridian filter; instead it discusses the G2 and G2X filters.**
21 **Deny that the FDA required specific testing. See Ex. 5 at 51:15-17; See also Bard**
22 **SOF Ex. B at Ex. 2. Bard first submitted their proposed animal study protocol to the**
23 **FDA at a Feb. 2009 pre-IDE meeting. Here Bard is providing FDA with an update to**
24 **the previously submitted proposed animal study protocol.**

25 476. FDA agreed to review BPV's proposed animal study protocol, and asked
26 BPV to submit the proposed protocol by way of submitting a formal pre-Investigational
27 Device Exemption ("IDE") meeting request. Ex. B, Van Vleet Decl. at ¶ 11.

1 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 2 **is reported to have said and what the conversation was reported to entail. Subject to**
 3 **this objection, admit in part, deny in part. Admit that the document attributes this**
 4 **statement to FDA, but deny that it was *in addition* to information required as part of**
 5 **the 510(k) clearance process.**

6 477. On December 3, 2009, in response to FDA's request, BPV provided the
 7 agency with a pre-IDE meeting request, which described the fundamental scientific
 8 technology of the Meridian® Filter (which, at the time, was internally called "Eclipse
 9 Anchor" filter), the risk analysis used by BPV, a summary of the design verification and
 10 validation testing, and a description of the proposed animal study protocol, along with an
 11 actual draft of the proposed protocol. Ex. B, Van Vleet Decl. at ¶ 12.

12 **Objection. This statement mischaracterizes the document as one submitted "in**
 13 **response to FDA's request." On page 4, the document states "*the purpose of this pre-***
 14 ***IDE submission is to request confirmation from the Agency...*" (emphasis added). The**
 15 **FDA did not request this information; instead Bard is submitting in an effort to**
 16 **demonstrate to the FDA their Eclipse filter is substantially equivalent to its predicate**
 17 **device. Subject to that objection, deny that this submission was *in addition* to**
 18 **information that is required as part of the 510(k) clearance process.**

19 478. On January 8, 2010, BPV had a face-to-face meeting with FDA to discuss
 20 Bard's pre-IDE meeting request for the Meridian® Filter. Ex. B, Van Vleet Decl. at ¶ 13.

21 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 22 **is reported to have said and what the conversation was reported to entail. Subject to**
 23 **this objection, admit in part, deny in part. Admit that the document purports that**
 24 **Bard and FDA had a meeting on Jan. 8, 2010. Deny that the Meridian filter was**
 25 **discussed at the meeting; the document references the Eclipse filter.**

26 479. During that meeting, FDA stated that BPV's in vivo animal study on
 27 Meridian® Filter would be required to (a) include animals that are seen by the
 28 veterinarian, (b) be performed to Good Laboratory Practices standards, and (c) use

1 animals with IVCs that are comparable in size to human IVCs. Ex. B, Van Vleet Decl. at
2 ¶ 13.

3 **Objection. This statement contains inadmissible hearsay as to what the FDA**
4 **is reported to have said and what the conversation was reported to entail. Subject to**
5 **this objection, deny that the Meridian filter was discussed at the meeting; the**
6 **document references the Eclipse filter. Deny that the FDA imposed specific**
7 **requirements. Ex. 5 at 51:15-17. The referenced document discusses expectations,**
8 **concerns, suggestions and recommendations. Deny that the expectation, concerns,**
9 **suggestions and recommendations discussed *increased* or *added* to the information**
10 **that is required as part of the 510(k) clearance process.**

11 480. FDA also asked BPV to conduct an acute animal study to test the delivery
12 system. Ex. B, Van Vleet Decl. at ¶ 13.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
14 **is reported to have asked and what the conversation was reported to entail, and**
15 **further the statement mischaracterizes the document relied upon. Subject to these**
16 **objections, admit in part, deny in part. Admit that the document purports to reflect**
17 **that the FDA indicated it would *expect to see* an animal study with the modified**
18 **delivery system in response to Bard informing the FDA “the delivery system used in**
19 **the chronic animal study is not the one we will ultimately market.” Deny FDA asked**
20 **Bard to conduct an acute animal study. Deny that the FDA imposed specific**
21 **requirements. Ex. 5 at 51:15-17.**

22 481. FDA also stated that BPV would be required to include in its 510(k) the
23 animal study reports by the outside consulting company, LyChron LLC, which was to
24 assist BPV with the animal studies. Ex. B, Van Vleet Decl. at ¶ 13.

25 **Objection. This statement contains inadmissible hearsay as to what the FDA**
26 **is reported to have asked and what the conversation was reported to entail, and**
27 **further the statement mischaracterizes the document relied upon. Subject to these**
28 **objections, admit in part, deny in part. Admit that the document purports to reflect**

1 that the FDA indicated that “in section 7.3.2. of the animal study, it is indicated that
2 animal illness and abnormalities are record. These reports should be provided with
3 the submission,” but deny that the FDA *required* this information or that this
4 information was *in addition* to information required as part of the 510(k) clearance
5 process.

6 482. FDA additionally asked BPV about the company’s flat plate fatigue testing
7 that it intended to conduct on the device. Ex. B, Van Vleet Decl. at ¶ 13.

8 **Objection.** This statement contains inadmissible hearsay as to what the FDA
9 is reported to have asked and what the conversation was reported to entail, and
10 further the statement mischaracterizes the document relied upon. Subject to these
11 objections, deny. The document states “Rob [Carr, Bard employee] then *explained*
12 the bench testing to be performed. Angela [FDA employee] asked for a *description* of
13 the test that will be performed and the acceptance criteria for the flat plate fatigue.”
14 (emphasis added). Deny that the FDA imposed specific requirements. Deny the FDA
15 “additionally asked” about testing Bard intended to conduct.

16 483. BPV responded by providing FDA with information concerning the
17 acceptance criteria for that test (10 year equivalent of valsalva, or no failures in 4,000,000
18 cycles at a rate and deflection simulating coughing), which the FDA stated would be
19 acceptable. Ex. B, Van Vleet Decl. at ¶ 13.

20 **Objection.** This statement contains inadmissible hearsay as to what the FDA
21 is reported to have said and what the conversation was reported to entail. Subject to
22 said objection, admit that Bard indicated testing “will have the same acceptance
23 criteria as previous testing” and the FDA replied “that this would be okay.”

24 484. On August 31, 2010 BPV submitted its Traditional 510(k) submission
25 (K102511) to FDA for the Meridian® Filter System -- Jugular/Subclavian Delivery Kit.
26 Ex. B, Van Vleet Decl. at ¶ 14.

27 **Admit.**
28

1 485. In the Meridian® 510(k) submission, BPV described for FDA the battery of
2 *in vitro* testing conducted by BPV on the Meridian® Filter, including fatigue resistance,
3 anchor weld tensile strength, cephalad migration resistance, caudal migration resistance,
4 filter centering (tilt), corrosion resistance, biocompatibility, and other testing. Ex. B, Van
5 Vleet Decl. at ¶ 14.

6 **Admit in part, deny in part. Admit Bard described the testing they conducted,**
7 **deny that the FDA required specific testing or that Bard conducted a “battery” of**
8 **testing. Deny that this testing was completed *in addition* to information required as**
9 **part of the 510(k) clearance process.**

10 486. BPV additionally provided FDA with summary data sheets of this *in vitro*
11 testing. Ex. B, Van Vleet Decl. at ¶ 14.

12 **Admit in part, deny in part. Admit Bard provided FDA with a summary data**
13 **sheets of their *in vitro* testing, but deny providing this information to the FDA was *in***
14 ***addition* to information required as part of the 510(k) clearance process.**

15 487. These tests were conducted as required under 21 C.F.R. 870.3375 (which is
16 a regulation specific to cardiovascular intravascular filters) and Special Control (1), which
17 requires manufacturers to follow ISO 10993 “Biological Evaluation of Medical Devices
18 Part I: Evaluation and Testing.” Ex. B, Van Vleet Decl. at ¶ 14.

19 **Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. The**
20 **regulation cited are general, not specific, special controls which applies generally to**
21 **all implantable medical devices and does not describe or establish requirements for**
22 **safety or effectiveness for any particular medical device including any IVC filters.**
23 **See Ex. 3 at 19.**

24 488. Along with describing the *in vitro* testing conducted by BPV on the
25 Meridian® Filter, BPV attached to its 510(k) submission various reports of
26 biocompatibility testing that had been performed. Ex. B, Van Vleet Decl. at ¶ 14.

1 **Admit in part, deny in part. Admit Bard included their deny biocompatibility**
 2 **testing results, but deny that providing this information to the FDA was *in addition***
 3 **to information required as part of the 510(k) clearance process.**

4 489. In the submission, BPV also described for FDA the in vivo animal testing
 5 conducted by the company on the Meridian® Filter. Ex. B, Van Vleet Decl. at ¶ 14.

6 **Admit.**

7 490. That testing assessed retrievability, fatigue resistance, cephalad migration
 8 resistance, caudal migration resistance, penetration resistance, perforation, filter centering
 9 (tilt), and other attributes of the device. Ex. B, Van Vleet Decl. at ¶ 14.

10 **Admit in part, deny in part. Admit Bard included their deny biocompatibility**
 11 **testing results, but deny that providing this information to the FDA was *in addition***
 12 **to information required as part of the 510(k) clearance process.**

13 491. Along with describing the in vivo animal testing on the Meridian® Filter,
 14 BPV's 510(k) submission attached voluminous documents related to that animal testing,
 15 including protocols, test reports, and histology slides. Ex. B, Van Vleet Decl. at ¶ 14.

16 **Admit in part, deny in part. Admit that the documents started are attached;**
 17 **deny Bard's characterization of the documents being voluminous. Bard providing**
 18 **this information to the FDA was not *in addition* to information required as part of**
 19 **the 510(k) clearance process.**

20 492. Thereafter, on October 26, 2010, FDA sent BPV a letter requesting
 21 additional information before FDA could determine whether it could clear the Meridian®
 22 Filter. Ex. B, Van Vleet Decl. at ¶ 15.

23 **Admit with clarification that the FDA was merely asking Bard to cure**
 24 **deficiencies in its initial 510(k). The FDA specifically stated: "The deficiency**
 25 **identified above represents the issue we believe needs to be resolved before our**
 26 **review of your 510(k) submission can be successfully completed. In developing the**
 27 **deficiency, we carefully considered the statutory criteria ... for determining**
 28 **substantial equivalence of your device." Bard SOF Ex. A at Ex. 122. Deny the FDA**

1 was requiring or mandating any action by Bard other than complying with the
2 standard requirements for 510(k) submission.

3 493. In the letter, FDA directed BPV to provide additional information and
4 responses to 14 questions (many with multiple subparts) regarding device sterilization,
5 shelf-life testing, biocompatibility testing, fatigue testing, tensile strength testing,
6 migration testing, retrieval testing, corrosion testing, clot trapping efficiency, animal
7 testing, and device labeling. Ex. B, Van Vleet Decl. at ¶ 15.

8 **Admit in part, deny in part. Admit the October 26, 2010, FDA letter sought**
9 **supplementary information. Deny all other assertions and characterizations to the**
10 **extent they imply that the FDA established any *additional requirements* for**
11 **completing the 510(k) clearance process. The information requested is outlined**
12 **pursuant to 21 CFR 807 §§ 87 and 92 and Bard failed to submit it in its original**
13 **submission. In fact, FDA states “the deficiencies identified above represent the issues**
14 **that we believe need to be resolved before our review of your 510(k) submission can**
15 **be successfully completed.”**

16 494. In particular, FDA required BPV to perform additional testing. Ex. B, Van
17 Vleet Decl. at ¶ 15.

18 **Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny the**
19 **FDA was requiring or mandating any action by Bard other than complying with the**
20 **standard requirements for 510(k) submission.**

21 495. Specifically, FDA required Bard to perform corrosion testing on fatigued
22 filters (Question 9c), and to perform clot trapping testing (Question 11). Ex. B, Van Vleet
23 Decl. at ¶ 15.

24 **Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny the**
25 **FDA was requiring or mandating any action by Bard other than complying with the**
26 **standard requirements for 510(k) submission. In regards to question 9, the FDA**
27 **states “your summary did not include...”, “please provide the raw data, and “please**
28 **clarify whether testing was completed...if not please perform...”**

1 496. Furthermore, “to assess the safety of [the Meridian® Filter] in the [magnetic
2 resonance (“MR”)] environment,” FDA asked BPV to provide MR heating test results at
3 the location of the maximum heating for at least three different orientations to the incident
4 electrical field in two different systems (Question 12a). Ex. B, Van Vleet Decl. at ¶ 15.

5 **Objection. This statement contains inadmissible hearsay. Subject to said**
6 **objection, admit the FDA states “The RF heating results you provided do not**
7 **necessarily report the maximum heating location on your device. To assess the safety**
8 **of your device in the MR environment, FDA would like to know the location of the**
9 **maximum heating on your device for at least three different orientations relative to**
10 **the incident electrical field.” (emphasis added).**

11 497. Additionally, FDA directed BPV to provide various tests reports, including
12 sterilization testing (Question 1a), endotoxin testing (Question 1b), corrosion testing
13 (Question 9a), animal testing (Question 13). Ex. B, Van Vleet Decl. at ¶ 15.

14 **Objection. This statement contains inadmissible hearsay. Subject to said**
15 **objection, deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Further**
16 **deny the FDA was requiring or mandating any action by Bard other than complying**
17 **with the standard requirements for 510(k) submission.**

18
19 498. In particular, with regard to animal testing, FDA noted that it could not
20 assess BPV’s conclusions “about the chronic safety of the Meridian filter” based on the
21 animal study test reports provided. Ex. B, Van Vleet Decl. at ¶ 15.

22 **Objection. This statement contains inadmissible hearsay. Subject to said**
23 **objection, deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Further**
24 **deny the FDA was requiring or mandating any action by Bard other than complying**
25 **with the standard requirements for 510(k) submission. The FDA sought this**
26 **information to “determine the substantial equivalence of your [Bard’s] device.”**
27
28

1 499. FDA also asked BPV to provide manuscripts of the articles used by BPV to
2 develop the deformation distances for fatigue testing (Question 4b). Ex. B, Van Vleet
3 Decl. at ¶ 15.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit the FDA asked Bard to “describe the findings in these manuscripts**
6 **and how you derived your values from this data in these references as the FDA does**
7 **not agree that the chosen deformations are representative of the worst-case values in**
8 **these manuscripts.” Bard is responsible for compiling with the statutes that provide**
9 **the framework for a 501(k) submission per 21 C.F.R. 807 §§ 87 and 92; because Bard**
10 **failed to submit this data in its original submission, the FDA is requesting it as the**
11 **deficiencies “need to be resolved before our [FDA] review of your [Bard] 510(k)**
12 **submission can be successfully completed.”**

13 500. FDA further required BPV to describe BPV’s fatigue test setup and
14 apparatus and to explain why the testing is considered representative of the IVC (Question
15 4a). Ex. B, Van Vleet Decl. at ¶ 15.

16 **Objection. This statement contains inadmissible hearsay and the use of the**
17 **word “required” is misleading. Subject to said objections, admit in part, deny in**
18 **part. Admit the FDA asked Bard to “please describe” and “please explain how the**
19 **deformation imposed on the device was measured and monitored throughout the**
20 **test.” Deny that the FDA’s question established any *additional requirements* for**
21 **completing the 510(k) clearance process.**

22 501. FDA also asked BPV to describe and provide explanation for various
23 aspects of BPV’s migration resistance testing (Question 6a-6c). Ex. B, Van Vleet Decl. at
24 ¶ 15.

25 **Objection. This statement contains inadmissible hearsay. Subject to said**
26 **objection, admit that the FDA asked for this information because Bard failed to**
27 **submit this data in its original submission, pursuant to 21 C.F.R. 807 §§ 87 and 92.**
28 **The FDA states in the letter conclusion of its letter that “the deficiencies identified**

1 above represent issues that we believe need to be resolved before our [FDA] review
2 of your [Bard] 510(k) submission can be successfully completed.”

3 502. FDA also required BPV to make certain changes to the labeling of the
4 device regarding magnetic resonance imaging (“MRI”) compatibility (Question 12b),
5 latex use (Question 14a), and retrievability and the potential need for follow-up
6 monitoring (Question 14b). Ex. B, Van Vleet Decl. at ¶ 15.

7 **Objection. This statement contains inadmissible hearsay and the use of the**
8 **word “required” is misleading. Subject to said objections, deny that the FDA’s**
9 **question established any *additional requirements* for completing the 510(k) clearance**
10 **process. Labeling revisions and changes are negotiated between the FDA and a**
11 **manufacturer. See Ex. 11 at 92:1-4.**

12 503. FDA required BPV to provide responses to the above requests before the
13 agency could complete review of the company’s 510(k) submission. Ex. B, Van Vleet
14 Decl. at ¶ 15.

15 **Objection. This statement contains inadmissible hearsay and the use of the**
16 **word “required” is misleading. Subject to said objections, admit that the FDA was**
17 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**
18 **FDA’s questions do not establish any *additional requirements* for completing the**
19 **510(k) clearance process. In fact, the FDA states in the letter conclusion of their**
20 **letter that “the deficiencies identified above represent issues that we believe need to**
21 **be resolved before our FDA review of your [Bard] 510(k) submission can be**
22 **successfully completed.”**

23 504. In FDA’s letter, the agency stated that if BPV does not provide the
24 requested information (or a request for extension of time) within 30 days, the company’s
25 510(k) submission will be considered “withdrawn” and “deleted from [the agency’s]
26 system.” Ex. B, Van Vleet Decl. at ¶ 15.

27 **Admit that this information is lifted from the statute outlining the framework**
28 **for the 510(k) submission process. Specifically, 21 C.F.R. § 807.87(l) states “if you**

1 **submit the requested information after 30 days it will be considered and processed as**
 2 **a new 510(k)."**

3 505. Subsequently, FDA and BPV had a teleconference on November 12, 2010
 4 to discuss certain of the issues raised by FDA in its October 26 letter. Ex. B, Van Vleet
 5 Decl. at ¶ 16.

6 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 7 **is reported to have said and what the conversation was reported to entail. Subject to**
 8 **said objection, admit that the document purports that Bard will discuss with FDA**
 9 **issues raised by the FDA's October 26, 2010, "deficiency letter."**

10 506. In particular, BPV and FDA discussed FDA's desire to better understand
 11 BPV's development of the "worst case" values for its fatigue testing. Ex. B, Van Vleet
 12 Decl. at ¶ 16.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 14 **is reported to have said and what the conversation was reported to entail. Subject to**
 15 **said objection, admit in part, deny in part. Admit that the document suggests the**
 16 **FDA wanted more information on Bard's assumptions relating to worst case**
 17 **scenarios since the FDA did not agree with Bard that its chosen deformation**
 18 **reflected worst case scenarios. Deny all other assertions and characterizations to the**
 19 **extent they imply that the FDA's question established any *additional requirements* for**
 20 **completing the 510(k) clearance process. The FDA was seeking "adequate**
 21 **information described and required by to 21 CFR 807.87(l)."**

22 507. On November 16, 2010, BPV provided FDA with an email and attachments
 23 that explained BPV's fatigue testing setup and testing parameters, which addressed
 24 Questions 4a-4c of FDA's October 26, 2010 letter. Ex. B, Van Vleet Decl. at ¶ 17.

25 **Admit.**

26 508. On December 8, 2010, BPV and FDA had a teleconference to further
 27 discuss FDA's questions about BPV's fatigue testing. Ex. B, Van Vleet Decl. at ¶ 18.

1 **Objection. This statement contains inadmissible hearsay as to what the FDA**
2 **is reported to have said and what the conversation was reported to entail. Subject to**
3 **said objection, admit that the document purports that Bard and FDA had a**
4 **telephone conference on Dec. 8, 2010.**

5 509. In particular, in follow-up to BPV's November 16 email, FDA asked further
6 questions regarding how BPV's fatigue testing was monitored to ensure proper
7 displacement, as well as questions about how BPV derived its fatigue deformation
8 distance based on literature. Ex. B, Van Vleet Decl. at ¶ 18.

9 **Objection. This statement contains inadmissible hearsay as to what the FDA**
10 **is reported to have said and what the conversation was reported to entail. Subject to**
11 **said objection, admit that the referenced document attributes these statements to the**
12 **FDA.**

13 510. BPV responded by describing in further detail the fatigue testing and how
14 BPV ensured that the filters were constantly and consistently fatigued during testing. Ex.
15 B, Van Vleet Decl. at ¶ 18.

16 **Objection. This statement contains inadmissible hearsay as to what the FDA**
17 **is reported to have said and what the conversation was reported to entail. Subject to**
18 **said objection, admit in part, deny in part. Admit the referenced document shows**
19 **Bard answering FDA's questions regarding the fatigue testing. Deny that the**
20 **referenced document attributes the second statement to Bard, "how BPV ensured**
21 **that the filters were constantly and consistently fatigued during testing." This**
22 **statement was made by FDA's Dr. Ibrahim, not by Bard. Dr. Ibrahim emphasized**
23 **the importance of ensuring the device is experiencing the deformation that the test**
24 **equipment is set to.**

25 511. BPV also further explained the literature basis for selecting the fatigue
26 deformation distance utilized in the test. Ex. B, Van Vleet Decl. at ¶ 18.

27 **Objection. This statement contains inadmissible hearsay as to what the FDA**
28 **is reported to have said and what the conversation was reported to entail. Subject to**

1 said objection, admit that the referenced document attributes these statements to
 2 Bard. Bard addressed its deficiency and the reason for explaining the literature to
 3 the FDA: “John VanVleet responded that BPV *did not do a good job linking the*
 4 *deflecting back to the Murphy article, and the loop would be closed in the formal*
 5 *response [Bard’s response to the Oct. 26th deficiency letter].” (emphasis added).*

6 512. On December 27, 2010, BPV sent FDA its official response to FDA’s
 7 questions of October 26, 2010. Ex. B, Van Vleet Decl. at ¶ 19.

8 **Admit.**

9 513. In response to FDA’s request (Question 9c), BPV performed additional
 10 corrosion testing on fatigued filters, and submitted the results of that test to FDA with the
 11 letter. Ex. B, Van Vleet Decl. at ¶ 19.

12 **Objection. Mischaracterizes the word “additional.” Subject to that objection,**
 13 **admit in part, deny in part. Admit Bard submitted the test results. Deny that the**
 14 **FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
 15 **characterizations to the extent they imply that the FDA’s request established any**
 16 ***additional requirements* for completing the 510(k) clearance process. The information**
 17 **requested was in response to deficiencies in Bard’s 510(k) submission. The FDA was**
 18 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

19 514. Additionally, in response to FDA’s request (Question 11), BPV had
 20 performed clot trapping efficiency testing. Ex. B, Van Vleet Decl. at ¶ 19.

21 **Admit in part, deny in part. Admit Bard submitted the test results. Deny that**
 22 **the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
 23 **characterizations to the extent they imply that the FDA’s request established any**
 24 ***additional requirements* for completing the 510(k) clearance process. The information**
 25 **requested was in response to deficiencies in Bard’s 510(k) submission. The FDA was**
 26 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

27 515. BPV described the testing performed, and provided FDA with a copy of the
 28 clot trapping efficiency test report. Ex. B, Van Vleet Decl. at ¶ 19.

1 **Admit in part, deny in part. Admit Bard described and submitted the test**
 2 **results. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all**
 3 **other assertions and characterizations to the extent they imply that the FDA’s**
 4 **request established any *additional requirements* for completing the 510(k) clearance**
 5 **process. The information requested was in response to deficiencies in Bard’s 510(k)**
 6 **submission. The FDA was seeking “adequate information described and required by**
 7 **to 21 CFR 807.87(l).”**

8 516. In response to FDA’s safety questions regarding the device in the MR
 9 environment (Question 12a), BPV performed additional analyses and testing to determine
 10 the maximum heating location on the device. Ex. B, Van Vleet Decl. at ¶ 19.

11 **Objection. Mischaracterizes the word “additional.” Subject to that objection,**
 12 **admit in part, deny in part. Admit Bard submitted the test results. Deny that the**
 13 **FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
 14 **characterizations to the extent they imply that the FDA’s request established any**
 15 ***additional requirements* for completing the 510(k) clearance process. The information**
 16 **requested was in response to deficiencies in Bard’s 510(k) submission. The FDA was**
 17 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

18 517. To do this, BPV performed tests to determine the temperature change at 4
 19 different locations using 3 different filter orientations (90 degrees, 180 degrees, and 270
 20 degrees) using thermometry probes in both the 1.5-Tesla and 3-Tesla settings. Ex. B, Van
 21 Vleet Decl. at ¶ 19.

22 **Admit.**

23 518. BPV further provided FDA with the various test reports and medical
 24 literature that FDA had requested (Questions 1a, 1b, 4b, 9a, 13). Ex. B, Van Vleet Decl.
 25 at ¶ 19.

26 **Admit in part, deny in part. Admit Bard provided the FDA with medical**
 27 **literature. Deny all other assertions and characterizations to the extent they imply**
 28 **that the FDA’s request established any *additional requirements* for completing the**

1 **510(k) clearance process. The information requested was in response to deficiencies**
 2 **in Bard's 510(k) submission. The FDA was seeking "adequate information described**
 3 **and required by to 21 CFR 807.87(l)."**

4 519. BPV also described in detail the BPV's fatigue testing and migration
 5 resistance testing (Questions 4a, 6a-6c). Ex. B, Van Vleet Decl. at ¶ 19.

6 **Admit.**

7 520. Finally, BPV made changes to the Meridian® instructions for use ("IFU")
 8 and patient brochure as required by FDA (Questions 12b, 14a, 14b). Ex. B, Van Vleet
 9 Decl. at ¶ 19.

10 **Objection. Misleading as to the word "required." Subject to that objection,**
 11 **admit in part, deny in part. Admit that Bard made certain changes to the IFU. Deny**
 12 **that the FDA "required" this revision. Labeling revisions and changes are negotiated**
 13 **between the FDA and a manufacturer, not required. See Ex. 11 at 92:1-4.**

14 521. On February 1, 2011, FDA sent BPV a second letter requesting information
 15 necessary to determine whether it could clear the Meridian® Filter. Ex. B, Van Vleet
 16 Decl. at ¶ 20.

17 **Admit in part, deny in part. Admit the Feb. 1, 2011 FDA sent a second**
 18 **deficiency letter regarding the Meridian device (the first deficiency letter was sent on**
 19 **Oct. 26, 2010). Deny all other assertions and characterizations to the extent they**
 20 **imply that the FDA's established any *additional requirements* for completing the**
 21 **510(k) clearance process. The information requested is outlined pursuant to 21**
 22 **C.F.R. 807 §§ 87 and 92 and Bard failed to submit it in its original submission. In**
 23 **fact, FDA states "the deficiencies identified above represent the issues that we believe**
 24 **need to be resolved before our review of your 510(k) submission can be successfully**
 25 **completed."**

26 522. In the letter, FDA directed BPV to provide additional information and
 27 responses to 13 questions regarding shelf-life testing, carcinogenicity testing, toxicity
 28

1 testing, fatigue testing, migration testing, retrieval force, corrosion testing, clot trapping
2 efficiency testing, and device labeling. Ex. B, Van Vleet Decl. at ¶ 20.

3 **Objection. Mischaracterizes the word “additional.” Subject to that objection,**
4 **admit in part, deny in part. Admit Bard submitted the test results. Deny that the**
5 **FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
6 **characterizations to the extent they imply that the FDA’s request established any**
7 ***additional requirements* for completing the 510(k) clearance process. The information**
8 **requested was in response to deficiencies in Bard’s 510(k) submission. The FDA was**
9 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

10 523. In particular, FDA expressed “safety concerns” related to BPV’s corrosion
11 resistance testing of the Meridian® Filter. Ex. B, Van Vleet Decl. at ¶ 20.

12 **Admit. The information requested was in response to deficiencies in Bard’s**
13 **510(k) submission. The FDA sought this information to “determine the substantial**
14 **equivalence of your [Bard’s] device.”**

15 524. The agency required BPV to “address safety concerns related to the poor
16 corrosion resistance” by performing additional “chemical characterization of the
17 passivation layer of [Meridian® Filter] (atomic composition vs. depth) and nickel leach
18 testing on pre- and post-fatigue devices” (Question 8). Ex. B, Van Vleet Decl. at ¶ 20.

19 **Objection. Mischaracterizes the word “additional.” Subject to that objection,**
20 **admit that the FDA requested additional information relating to poor corrosion**
21 **resistance. The information requested was in response to deficiencies in Bard’s**
22 **510(k) submission. The FDA sought this information to “determine the substantial**
23 **equivalence of your [Bard’s] device.”**

24 525. FDA also asked BPV to provide the corrosion rate and to provide further
25 explanation regarding that rate. Ex. B, Van Vleet Decl. at ¶ 20.

26 **Admit.**

27 526. Furthermore, FDA required BPV to submit images of post-fatigued filters
28 for the agency’s review (Question 5). Ex. B, Van Vleet Decl. at ¶ 20.

1 **Objection. Misleading as to the word “required.” Subject to that objection,**
 2 **admit that the FDA requested that Bard provide the images. The information**
 3 **requested was in response to deficiencies in Bard’s 510(k) submission.**

4 527. Additionally, FDA required BPV to modify its protocol for shelf life testing
 5 (Question 1). Ex. B, Van Vleet Decl. at ¶ 20.

6 **Objection. Misleading as to the word “required.” Subject to that objection,**
 7 **admit in part, deny in part. Admit the FDA requested that Bard modify its protocol**
 8 **to include shelf-life testing. Deny that the FDA required specific tests. See Ex. 5 at**
 9 **51:15-17. Deny all other assertions and characterizations to the extent they imply**
 10 **that the FDA’s request established any *additional requirements* for completing the**
 11 **510(k) clearance process.**

12 528. FDA also required BPV to repeat chromosomal aberration testing or provide
 13 justification regarding the presence or absence of genotoxic extractable in polar extracts
 14 under certain conditions (Question 3). Ex. B, Van Vleet Decl. at ¶ 20.

15 **Objection. Misleading as to the word “required.” Subject to that objection,**
 16 **admit in part, deny in part. Admit that the FDA requested that Bard repeat the**
 17 **testing “unless further justification” for the subject testing could be provided. Deny**
 18 **that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions**
 19 **and characterizations to the extent they imply that the FDA’s request established**
 20 **any *additional requirements* for completing the 510(k) clearance process.**

21 529. FDA also required BPV to repeat clot trapping efficiency testing using a
 22 shower of clots of multiple sizes (Question 10). Ex. B, Van Vleet Decl. at ¶ 20.

23 **Objection. Misleading as to the word “required.” Subject to that objection,**
 24 **admit in part, deny in part. Admit that the FDA requested that Bard repeat the**
 25 **testing “unless further justification” for the subject testing could be provided. Deny**
 26 **that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions**
 27 **and characterizations to the extent they imply that the FDA’s request established**
 28 **any *additional requirements* for completing the 510(k) clearance process.**

1 530. FDA also required BPV to further revise its labeling regarding MRI
2 compatibility and absorption rate (Questions 12 & 13). Ex. B, Van Vleet Decl. at ¶ 20.

3 **Objection. Misleading as to the word “required.” Subject to that objection,**
4 **admit in part, deny in part. Admit that the FDA requested that Bard modify its**
5 **labeling relating to Magnetic Resonance (MR) Environment (though FDA did not**
6 **provide specific language for this) and absorption rates. Labeling revisions and**
7 **changes are negotiated between the FDA and a manufacturer. See Ex. 11 at 92:1-4.**

8 531. FDA required BPV to provide responses to the above requests before the
9 agency could complete review of the company’s 510(k) submission. Ex. B, Van Vleet
10 Decl. at ¶ 20.

11 **Objection. Misleading as to the word “required.” Subject to that objection,**
12 **admit in part, deny in part. Admit that the FDA indicated to Bard that the requested**
13 **information was needed for FDA to complete its review of Bard’s submission. Deny**
14 **all other assertions and characterizations to the extent they imply that the FDA’s**
15 **FDA’s request established any *additional requirements* for completing the 510(k)**
16 **clearance process. In fact, FDA states “the deficiencies identified above represent the**
17 **issues that we believe need to be resolved before our review of your 510(k)**
18 **submission can be successfully completed.”**

19 532. In FDA’s letter, the agency stated that if BPV does not provide the
20 requested information (or a request for extension of time) within 30 days, the company’s
21 510(k) submission will be considered “withdrawn” and “deleted from [the agency’s]
22 system.” Ex. B, Van Vleet Decl. at ¶ 20.

23 **Admit. This information is lifted from the statute outlining the framework for**
24 **the 510(k) submission process. Specifically, 21 C.F.R. § 807.87(l) states “if you do not**
25 **submit the requested information after 30 days it will be considered and processed as**
26 **a new 510(k).”**

1 533. On February 10, 2011, BPV and FDA had a conference call to address
2 certain of FDA's questions from its February 1, 2011 Letter. Ex. B, Van Vleet Decl. at ¶
3 21.

4 **Objection. This statement contains inadmissible hearsay as to what the FDA**
5 **is reported to have said and what the conversation was reported to entail. Subject to**
6 **said objection, admit that the document relied upon states that a call between Bard**
7 **and FDA occurred on Feb. 10, 2011.**

8 534. During the meeting, FDA and BPV discussed FDA's various questions set
9 forth in the February 1, 2011 Letter so that BPV could better understand FDA's concerns
10 and provide appropriate responses. Ex. B, Van Vleet Decl. at ¶ 21.

11 **Objection. This statement contains inadmissible hearsay as to what the FDA**
12 **is reported to have said and what the conversation was reported to entail. Subject to**
13 **said objection, admit that the document relied upon suggests the purpose of the**
14 **meeting was to discuss the FDA's questions. Specifically, "during this call, the**
15 **deficiencies where discussed that were not related to biocompatibility or corrosion. A**
16 **subsequent call will occur with the biocompatibility and material science experts."**

17 535. A week later, on February 17, 2011, BPV and FDA had a conference call to
18 address FDA's biocompatibility and corrosion testing questions from its February 1, 2011
19 Letter. Ex. B, Van Vleet Decl. at ¶ 22.

20 **Objection. This statement contains inadmissible hearsay as to what the FDA**
21 **is reported to have said and what the conversation was reported to entail. Subject to**
22 **said objection, admit that the document relied upon suggests that the conference was**
23 **to discuss deficiencies related to biocompatibility and corrosion testing.**

24 536. Regarding the issue whether BPV would need to repeat chromosomal
25 aberration testing (Question 3), BPV identified for FDA certain test reports already
26 provided to the agency regarding this biocompatibility concern. Ex. B, Van Vleet Decl. at
27 ¶ 22.

Objection. This statement contains inadmissible hearsay as to what the FDA is reported to have said and what the conversation was reported to entail. Subject to said objection, admit that the document relied upon that the referenced document makes this reference. Deny all other assertions and characterizations to the extent they imply that the FDA's request established any *additional requirements* for completing the 510(k) clearance process.

537. FDA stated that it would "review the report and let BPV know if any additional testing would be required." Ex. B, Van Vleet Decl. at ¶ 22.

Objection. This statement contains inadmissible hearsay as to what the FDA is reported to have said and what the conversation was reported to entail. Subject to said objection, admit that the document relied upon attributes this statement to FDA.

538. In a February 17-22, 2011 email string, upon reviewing the test report, FDA indicated that BPV would be required to repeat the chromosomal aberration testing with water only under 70 degrees C for 24 hours and to further identify any compounds detected. Ex. B, Van Vleet Decl. at ¶ 22.

Objection. Misleading as to the word "required." Subject to that objection, deny. This option was provided by the FDA to Bard to justify not repeating the Chromosomal Aberration test and to address the deficiency. Bard SOF Ex. B at 15, BPVEFILTER-01-01853704.

539. Regarding Question 9 concerning BPV's galvanic corrosion testing, FDA stated that "surface characterization and nickel leaching are the only tests that can be done, and are the tests the FDA finds acceptable" to address galvanic corrosion. Ex. B, Van Vleet Decl. at ¶ 22.

Unable to admit or deny based on the submitted document. The quoted text not does appear in the referenced document or the proceeding document in Van Vleet Decl. at ¶ 23.

1 540. In response, BPV committed to performing testing regarding atomic
2 composition versus depth and nickel leaching out to 60 days. Ex. B, Van Vleet Decl. at
3 ¶ 22.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, deny. The quoted text is not found within the referenced document. To the**
6 **extent Bard meant to attribute this statement to Van Vleet Decl. at ¶ 23, objection,**
7 **this statement contains inadmissible hearsay. Subject to said objection, admit in**
8 **part, deny in part. Admit Bard agreed to perform 60-day NI leach testing. Deny that**
9 **the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
10 **characterizations to the extent they imply that the FDA’s request established any**
11 ***additional requirements* for completing the 510(k) clearance process. The information**
12 **requested was in response to deficiencies in Bard’s 510(k) submission. The FDA was**
13 **seeking “adequate information described and required by to 21 CFR 807.87(l).”**

14 541. BPV also stated it would consult with its corrosion consultant regarding the
15 corrosion testing to discuss repeating the testing until a steady state is reached. Ex. B,
16 Van Vleet Decl. at ¶ 22.

17 **Objection. This statement contains inadmissible hearsay. Subject to said**
18 **objection, deny. The quoted text is not found within the referenced document. To the**
19 **extent Bard meant to attribute this statement to Van Vleet Decl. at ¶ 23, admit.**

20 542. On May 17, 2011, BPV had a face-to-face meeting with FDA to discuss
21 Questions 8 and 9 from FDA’s February 1, 2011 Letter. Ex. B, Van Vleet Decl. at ¶ 23.

22 **Objection. This statement contains inadmissible hearsay as to what the FDA**
23 **is reported to have said and what the conversation was reported to entail. Subject to**
24 **said objection, admit that the document relied upon indicates this meeting occurred.**

25 543. During the meeting, BPV provided a 70-slide PowerPoint presentation that
26 summarized BPV’s efforts regarding corrosion testing, atomic composition v. depth,
27 galvanic corrosion, corrosion rate, and nickel leaching. Ex. B, Van Vleet Decl. at ¶ 23.

1 **Objection. This statement contains inadmissible hearsay as to what the BPV**
2 **is reported to have said and what the conversation was reported to entail. Subject to**
3 **said objection, admit that the document relied upon is a 70-page PowerPoint**
4 **presentation that includes the listed subject matters.**

5 544. This presentation included detailed charts and graphs of BPV's corrosion
6 testing efforts, as well as summaries of FDA's requests and BPV's responses to date
7 regarding the Meridian® Filter. Ex. B, Van Vleet Decl. at ¶ 23.

8 **Admit in part, deny in part. Admit the PowerPoint presentation includes**
9 **charts and graphs of the corrosion testing are in response to deficiencies in Bard's**
10 **510(k) submission. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
11 **Deny that the FDA's request established any *additional requirements* for completing**
12 **the 510(k) clearance process.**

13 545. With respect to galvanic corrosion testing, FDA asked BPV to repeat
14 galvanic corrosion on 6 straight anchor/wire couples and 6 offset anchor/wire couples.
15 Ex. B, Van Vleet Decl. at ¶ 23.

16 **Objection. This statement contains inadmissible hearsay as to what the FDA**
17 **is reported to have said and what the conversation was reported to entail. Subject to**
18 **said objection, admit that the document relied upon attributes this statement to the**
19 **FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny that the**
20 **FDA's request established any *additional requirements* for completing the 510(k)**
21 **clearance process.**

22 546. FDA also asked BPV conduct plots that show the galvanic current and
23 mixed potentials for the couples. Ex. B, Van Vleet Decl. at ¶ 23.

24 **Objection. This statement contains inadmissible hearsay as to what the FDA**
25 **is reported to have said and what the conversation was reported to entail. Subject to**
26 **said objection, admit in part, deny in part. Admit that the document attributes this**
27 **statement to the FDA. Deny that the FDA's request established any additional**
28 **requirements for completing the 510(k) clearance process.**

1 547. With respect to pitting corrosion, FDA directed BPV to re-plot CCP plots
2 and discuss any noise. Ex. B, Van Vleet Decl. at ¶ 23.

3 **Objection. This statement contains inadmissible hearsay as to what the FDA**
4 **is reported to have said and what the conversation was reported to entail.**
5 **Additionally, the statement is misleading as to the term “directed.” Subject to said**
6 **objections, admit in part, deny in part. Admit that the document attributes this**
7 **statement to FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
8 **Deny that the FDA’s request established any additional requirements for completing**
9 **the 510(k) clearance process.**

10 548. With respect to nickel leach testing, FDA required BPV to perform Ni
11 Leach testing on 5 non-fatigued filters from a single ingot. Ex. B, Van Vleet Decl. at ¶
12 23.

13 **Objection. This statement contains inadmissible hearsay as to what the FDA**
14 **is reported to have said and what the conversation was reported to entail.**
15 **Additionally, the statement is misleading as to the term “required.” Subject to said**
16 **objections, admit in part, deny in part. Admit that the document attributes this**
17 **statement to FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
18 **Deny that the FDA’s request established any additional requirements for completing**
19 **the 510(k) clearance process.**

20 549. FDA also required BPV to evaluate 1 spiked Ni solution at day 14, and to
21 perform a calibration test. Ex. B, Van Vleet Decl. at ¶ 23.

22 **Objection. This statement contains inadmissible hearsay as to what the FDA**
23 **is reported to have said and what the conversation was reported to entail.**
24 **Additionally, the statement is misleading as to the term “required.” Subject to said**
25 **objections, admit in part, deny in part. Admit that the document attributes this**
26 **statement to FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
27 **Deny that the FDA’s request established any additional requirements for completing**
28 **the 510(k) clearance process.**

1 550. FDA also stated it would propose to BPV language for labeling. Ex. B, Van
2 Vleet Decl. at ¶ 23.

3 **Objection. This statement contains inadmissible hearsay as to what the FDA**
4 **is reported to have said and what the conversation was reported to entail. Subject to**
5 **said objection, admit in part, deny in part. Admit that the document attributes this**
6 **statement to FDA. Deny that the FDA “required” this revision. Labeling revisions**
7 **and changes are negotiated between the FDA and a manufacturer, not required. See**
8 **Ex. 11 at 92:1-4.**

9 551. In a May 20-23, 2011 email chain with FDA, BPV and FDA further
10 discussed a summary of the “list of required additional testing” FDA requested for BPV to
11 “fully address deficiencies eight and nine.” Ex. B, Van Vleet Decl. at ¶ 24.

12 **Objection. The word “additional” is a mischaracterization. Subject to that**
13 **objection, admit in part, deny in part. Admit that Bard sent an email to FDA list of**
14 **the testing. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all**
15 **other assertions and characterizations to the extent they imply that the FDA’s**
16 **request established any *additional requirements* for completing the 510(k) clearance**
17 **process. The information requested was in response to deficiencies in Bard’s 510(k)**
18 **submission. FDA was seeking “adequate information described and required by to**
19 **21 CFR 807.87(l).”**

20 552. FDA confirmed that it was requiring BPV to do the following regarding
21 galvanic corrosion testing: repeat galvanic corrosion on 6 straight anchor/wire couples
22 and 6 offset anchor / wire couples; Only the galvanic test would be performed, not the
23 LPR and Tafel test; and plots would show the galvanic current and mixed potentials for
24 the couples. Ex. B, Van Vleet Decl. at ¶ 24.

25 **Objection. Statement is misleading as to the term “required.” Subject to said**
26 **objection, admit in part, deny in part. Admit that the FDA confirmed the testing to**
27 **be completed to resolve the deficiencies. Deny that the FDA used the word**
28 **“required.” Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny**

1 all other assertions and characterizations to the extent they imply that the FDA’s
 2 request established any *additional requirements* for completing the 510(k) clearance
 3 process. The information requested was in response to deficiencies in Bard’s 510(k)
 4 submission. FDA was seeking “adequate information described and required by to
 5 21 CFR 807.87(l).”

6 553. FDA confirmed that it was requiring BPV to do the following regarding
 7 pitting corrosion: re-plot CCP plots on the same scale and discuss any noise. Ex. B, Van
 8 Vleet Decl. at ¶ 24.

9 **Objection.** Statement is misleading as to the term “required.” Subject to said
 10 objection, admit in part, deny in part. Admit that the FDA confirmed the testing to
 11 be completed to resolve the deficiencies. Deny that the FDA used the word
 12 “required.” Deny that the FDA required specific tests. *See Ex. 5 at 51:15-17.* Deny
 13 all other assertions and characterizations to the extent they imply that the FDA’s
 14 request established any *additional requirements* for completing the 510(k) clearance
 15 process. The information requested was in response to deficiencies in Bard’s 510(k)
 16 submission. FDA was seeking “adequate information described and required by to
 17 21 CFR 807.87(l).”

18 554. FDA confirmed that it was requiring BPV to do the following regarding
 19 nickel leach testing: 5 non-fatigued filters would be tested, one filter would be tested per
 20 vial, and BPV would provide a description of the manufacturing controls related to the
 21 surface to the device. Ex. B, Van Vleet Decl. at ¶ 24.

22 **Objection.** Statement is misleading as to the term “required.” Subject to said
 23 objection, admit in part, deny in part. Admit that the FDA confirmed the testing to
 24 be completed to resolve the deficiencies. Deny that the FDA used the word
 25 “required.” Deny that the FDA required specific tests. *See Ex. 5 at 51:15-17.* Deny
 26 all other assertions and characterizations to the extent they imply that the FDA’s
 27 request established any *additional requirements* for completing the 510(k) clearance
 28 process. The information requested was in response to deficiencies in Bard’s 510(k)

1 **submission. FDA was seeking “adequate information described and required by to**
 2 **21 CFR 807.87(l).”**

3 555. FDA confirmed that it was requiring BPV to do the following regarding
 4 nickel leach calibration test: 1 spiked solution of 50µg/Liter would be evaluated at Day
 5 14. Ex. B, Van Vleet Decl. at ¶ 24.

6 **Objection. Statement is misleading as to the term “required.” Subject to said**
 7 **objection, admit in part, deny in part. Admit that the FDA confirmed the testing to**
 8 **be completed to resolve the deficiencies. Deny that the FDA used the word**
 9 **“required.” Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny**
 10 **all other assertions and characterizations to the extent they imply that the FDA’s**
 11 **request established any *additional requirements* for completing the 510(k) clearance**
 12 **process. The information requested was in response to deficiencies in Bard’s 510(k)**
 13 **submission. FDA was seeking “adequate information described and required by to**
 14 **21 CFR 807.87(l).”**

15 556. In addition, FDA provided BPV with the following proposed language to
 16 include in BPV’s Meridian® Filter IFU: “The [DEVICE NAME] consists of nickel-
 17 titanium alloy, which is generally considered safe. However, *in vitro* testing has
 18 demonstrated that nickel is released from this device for a minimum of 60 days. Patients
 19 who are allergic to nickel may have an allergic reaction to this device, especially those
 20 with a history of metal allergies. Certain allergic reactions can be serious; patients should
 21 be instructed to notify their physicians immediately if they suspect they are experiencing
 22 an allergic reaction such as difficulty in breathing or inflammation of the face or throat.
 23 Some patients may develop an allergy to nickel if this device is implanted. Some forms of
 24 nickel have also been associated with carcinogenicity (ability to cause cancer) in animal
 25 models. In humans, carcinogenicity has been demonstrated through an inhalation route
 26 (breathing nickel in), which will not occur in this procedure. The effect of other routes of
 27 exposure is not known, but the risk related to this device is considered small.” Ex. B, Van
 28 Vleet Decl. at ¶ 24.

1 **Admit Bard proposed the labeling language list above. Labeling revisions and**
2 **changes are negotiated between the FDA and a manufacturer, not required. *See Ex.***
3 **11 at 92:1-4.**

4 557. On May 23, 2011, BPV sent FDA the company's informal responses to
5 certain of FDA's questions from the February 1, 2011 letter. Ex. B, Van Vleet Decl. at ¶
6 25.

7 **Admit Bard sent FDA “informal responses to Meridian deficiencies 1-7 and**
8 **10-13” on February 1, 2011.**

9 558. In response to FDA's request (Question 1), BPV revised its shelf-life testing
10 protocol. Ex. B, Van Vleet Decl. at ¶ 25.

11 **Admit. The information requested was in response to deficiencies in Bard's**
12 **510(k) submission. The FDA's request did not establish any *additional requirements***
13 **for completing the 510(k) submission. The FDA was seeking “adequate information**
14 **described and required by to 21 CFR 807.87(l).”**

15 559. Additionally, in response to FDA's requests (Questions 3, 10), BPV
16 repeated its chromosomal aberration testing with an undiluted polar extract, and repeated
17 its clot trapping efficiency testing using a shower of clots of various diameters. Ex. B,
18 Van Vleet Decl. at ¶ 25.

19 **Admit. The information requested was in response to deficiencies in Bard's**
20 **510(k) submission. The FDA's request did not establish any additional requirements**
21 **for completing the 510(k) submission. The FDA was seeking “adequate information**
22 **described and required by to 21 CFR 807.87(l).”**

23 560. BPV also provided FDA with images of post-fatigued filters, as FDA had
24 requested (Question 5). Ex. B, Van Vleet Decl. at ¶ 25.

25 **Admit. The information requested was in response to deficiencies in Bard's**
26 **510(k) submission. FDA's request did not establish any additional requirements for**
27 **completing the 510(k) submission. FDA was seeking “adequate information**
28 **described and required by to 21 CFR 807.87(l).”**

1 561. Finally, BPV submitted draft revised labeling with updates for MRI
2 compatibility and absorption rate (Questions 12 & 13). Ex. B, Van Vleet Decl. at ¶ 25.

3 **Admit. Labeling revisions and changes are negotiated between the FDA and a**
4 **manufacturer, not required. See Ex. 11 at 92:1-4.**

5 562. On June 15, 2011, BPV sent FDA the company's informal responses to the
6 remaining questions from FDA's February 1, 2011 Letter. Ex. B, Van Vleet Decl. at ¶ 26.

7 **Deny. The date is incorrect. The referenced document purports that on June**
8 **16, 2011, BPV emailed FDA results from testing performed following the May 17th**
9 **meeting.**

10 563. In response to FDA's requests (Questions 8 & 9), and to address FDA's
11 safety concerns, BPV performed additional testing to submit to FDA. Ex. B, Van Vleet
12 Decl. at ¶ 26.

13 **Objection. Statement is misleading as to the term "additional." Subject to said**
14 **objection, admit in part, deny in part. Admit Bard performed testing to address**
15 **deficiencies in Bard's 510(k) submission. Deny the FDA's review was for**
16 **independent establishment of safety and effectiveness. The FDA sought this**
17 **information to "determine the substantial equivalence of your [Bard's] device."**
18 **Deny the referenced document represents this statement; Bard's response is not**
19 **included.**

20 564. These tests included atomic composition versus depth testing, 60-Day Ni
21 leach testing, additional Ni leach testing, a Ni calibration test, repeated galvanic corrosion
22 testing (done until a steady state was reached), and additional galvanic corrosion testing
23 using an increased sample size. Ex. B, Van Vleet Decl. at ¶ 26.

24 **Admit in part, deny in part. Admit Bard performed testing to address**
25 **deficiencies in Bard's 510(k) submission. Deny the referenced document represents**
26 **this statement; Bard's response is not included.**

27 565. BPV also agreed to conduct a Ni risk assessment. Test reports for each of
28 these tests were submitted. Ex. B, Van Vleet Decl. at ¶ 26.

1 **Admit in part, deny in part. Admit Bard performed testing to address**
 2 **deficiencies in Bard's 510(k) submission. Deny the referenced document represents**
 3 **this statement; Bard's response is not included.**

4 566. On June 22, 2011, BPV and FDA had a conference call to discuss BPV's
 5 June 15, 2011 response to the agency's February 1, 2011 Letter, and to specifically to
 6 discuss the results of BPV's additional testing conducted at FDA's request. Ex. B, Van
 7 Vleet Decl. at ¶ 27.

8 **Objection. This statement contains inadmissible hearsay as to what the FDA**
 9 **is reported to have said and what the conversation was reported to entail.**
 10 **Additionally, the statement is misleading as to the term "additional." Subject to said**
 11 **objections, admit in part, deny in part. Admit that the document attributes this**
 12 **statement to FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
 13 **Deny that the FDA's request established any additional requirements for completing**
 14 **the 510(k) clearance process.**

15 567. As a result of the meeting, and at FDA's request, BPV agree to include in its
 16 formal response the following: a discussion on the difference between the 60-day and 14-
 17 day data for non-fatigued devices; a table of the Ni release results; and a description of the
 18 equation used to describe the results. Ex. B, Van Vleet Decl. at ¶ 27.

19 **Objection. Statement contains inadmissible hearsay. Subject to said objection,**
 20 **admit that the referenced document makes this statement.**

21 568. On June 27, 2011, BPV sent FDA BPV's formal responses to FDA's
 22 questions from its February 1, 2011 Letter. Ex. B, Van Vleet Decl. at ¶ 28.

23 **Admit. On June 27, 2011 Bard mailed the FDA the formal responses and**
 24 **emailed a copy on June 28, 2011.**

25 569. This formal response included descriptions, summaries, and reports for all
 26 additional testing and analyses that the FDA required BPV to conduct before FDA could
 27 assess clearance of the Meridian® Filter, including: (a) modifying the stability protocol
 28 (Question 1), (b) repeated chromosomal aberration testing with undiluted polar extract at

1 70C for 24 hours (Question 3), (c) imaging at 40X magnification of fatigued filters, with
 2 BPV's justification for image location (Question 5), (d) providing composite (linear /
 3 transverse) modulus of *in-vivo* IVC compared to mock vessels utilized in migration
 4 testing, which FDA deemed acceptable (Question 6), (e) conducting retrieval force testing
 5 on predicate device the Eclipse® filter (Question 7), (f) conducting atomic composition
 6 versus depth and 60-day Ni leaching testing (Question 8), (g) conducting 14-day Ni leach
 7 testing on additional non-fatigued samples and a spiked Ni control (Question 8), (h)
 8 calculating corrosion rate in mils/year (Question 9), (i) performing galvanic corrosion
 9 testing until steady state was reached (Question 9), (j) additional galvanic corrosion
 10 testing with an increased galvanic corrosion sample size (Question 9), (k) repeating clot
 11 trapping efficiency testing using shower clot trapping test method (Question 10), (l)
 12 providing FDA with an experimental analysis demonstrating worst case heating location
 13 (Question 11), and (m) revised MRI labeling (Questions 11-13). Ex. B, Van Vleet Decl.
 14 at ¶ 28.

15 **Objection. This statement is misleading as to the term “required.” Subject to**
 16 **said objection, admit in part, deny in part. Admit that the document attributes this**
 17 **statement to FDA. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17.**
 18 **Deny that the FDA's request established any additional requirements for completing**
 19 **the 510(k) clearance process.**

20 570. Additionally, in response to FDA's request, BPV provided FDA with a
 21 sample Meridian® Filter for FDA to review. Ex. B, Van Vleet Decl. at ¶ 28.

22 **Plaintiffs cannot confirm from the referenced document that a sample was**
 23 **sent. Admit that a sample filter was requested and that Bard agreed to provide it.**

24 571. On August 16-17, 2011, FDA and BPV exchanged emails regarding FDA's
 25 proposal for still further changes to the Meridian® IFU, which BPV agreed to implement.
 26 Ex. B, Van Vleet Decl. at ¶ 29.

27 **Admit. Labeling revisions and changes are negotiated between the FDA and a**
 28 **manufacturer, not required. See Ex. 11 at 92:1-4.**

1 572. Specifically, FDA requested, and BPV agreed to implement, the following
2 changes to the Meridian® Filter IFU: The [DEVICE NAME] consists of nickel-titanium
3 alloy, which is generally considered safe. However, *in vitro* testing has demonstrated that
4 nickel is released from this device for a minimum of 60 days. Persons with allergic
5 reactions to nickel may suffer an allergic response to this implant, especially those with a
6 history of metal allergies. Some patients may develop an allergy to nickel if this device is
7 implanted. Certain allergic reactions can be serious. While devices that release nickel are
8 not expected to result in symptoms such as difficulty in breathing or inflammation of the
9 face or throat, if these types of allergic reactions occur, patients should be instructed to
10 seek immediate medical attention. Some forms of nickel have also been associated with
11 carcinogenicity (ability to cause cancer) in animal models. It is unknown whether nickel
12 released from implants will increase a patient's cancer risk. Ex. B, Van Vleet Decl. at ¶
13 29.

14 **Admit that the FDA “recommended some modifications to the nickel**
15 **language.” Admit the language is accurately quoted.**

16 573. On August 24, 2011, FDA sent BPV a letter clearing the Meridian® Filter
17 System -- Jugular/Subclavian Delivery Kit (K102511). Ex. B, Van Vleet Decl. at ¶ 30.

18 **Admit.**

19 574. In total, BPV's initial 510(k) submission for the Meridian® Filter System --
20 Jugular/Subclavian Delivery Kit (K102511), submitted August 31, 2010, was pending for
21 almost a full year before FDA cleared the device on August 24, 2011. Ex. B, Van Vleet
22 Decl. at ¶ 30.

23 **Plaintiffs cannot confirm from the referenced document the totality of time**
24 **for the FDA review of Bard's Meridian filter. Admit the device was cleared on Aug.**
25 **24, 2011.**

26 575. On August 27, 2011, BPV submitted its Special 510(k) submission to FDA
27 for the Meridian® Filter System - Femoral Delivery Kit. Ex. B, Van Vleet Decl. at ¶ 31.

28 **Admit.**

1 576. This 510(k) submission sought to make changes to the Meridian® Filter
2 delivery system only, not to the filter itself, to accommodate delivery via the femoral vein.
3 Ex. B, Van Vleet Decl. at ¶ 31.

4 **Admit.**

5 577. In the 510(k) submission, BPV described for FDA the *in-vitro* and *in-vivo*
6 testing conducted by BPV to support clearance of the filter with a femoral delivery
7 system. Ex. B, Van Vleet Decl. at ¶ 31.

8 **Admit.**

9 578. This included summaries of that testing, as well as various test protocols and
10 reports. Ex. B, Van Vleet Decl. at ¶ 31.

11 **Admit.**

12 579. On September 30, 2011, FDA sent BPV a letter requesting additional
13 information before FDA could determine whether it could clear the Meridian® Filter with
14 a femoral delivery system. Ex. B, Van Vleet Decl. at ¶ 32.

15 **Objection. Statement is misleading as to the word “additional.” Subject to that**
16 **objection, admit in part, deny in part. Admit FDA sent a letter to Bard on Sept. 20,**
17 **2011 outlining the deficiencies in their Special 510(k) submission. Deny all other**
18 **assertions and characterizations to the extent they imply that the FDA’s established**
19 **any *additional requirements* for completing the 510(k) clearance process. The**
20 **information requested is outlined pursuant to 21 CFR 807 §§ 87 and 92 and Bard**
21 **failed to submit it in its original submission.**

22 580. In particular, FDA asked for clarification regarding the overmold for the
23 storage tubing of the delivery system (Question 1). Ex. B, Van Vleet Decl. at ¶ 32.

24 **Admit.**

25 581. FDA also directed BPV to make certain revisions to BPV’s 510(k) summary
26 to better state the changes of the device compared to the predicates (Question 2). Ex. B,
27 Van Vleet Decl. at ¶ 32.

1 **Objection. Statement is misleading as to the word “directed.” Subject to said**
2 **objection, admit FDA requested that Bard revise language in the 510(k) summary to**
3 **“clearly identify the changes made to the delivery system” as a means of correcting**
4 **deficiencies in Bard’s submission. Bard SOF Ex. B at Ex. 33 (BPV-17-00147593).**

5 582. FDA required BPV to provide responses to the above requests before the
6 agency could complete review of the company’s 510(k) submission. Ex. B, Van Vleet
7 Decl. at ¶ 32.

8 **Admit. The information requested is in response to deficiencies in Bard’s**
9 **510(k) submission. The FDA sought this information to “determine the substantial**
10 **equivalence of your [Bard’s] device.” FDA was seeking “adequate information**
11 **described and required by to 21 CFR 807.87(l).”**

12 583. In FDA’s letter, the agency stated that if BPV does not provide the
13 requested information (or a request for extension of time) within 30 days, the company’s
14 510(k) submission will be considered “withdrawn” and “deleted from [the agency’s]
15 system.” Ex. B, Van Vleet Decl. at ¶ 32.

16 **Admit. This information is lifted from the statute outlining the framework for**
17 **the 510(k) submission process. Specifically, 21 C.F.R. § 807.87(l) states “if you**
18 **submit the requested information after 30 days it will be considered and processed as**
19 **a new 510(k).”**

20 584. On September 30, 2011, BPV provided its official response to FDA’s
21 questions. Ex. B, Van Vleet Decl. at ¶ 33.

22 **Admit.**

23 585. In its response, BPV clarified that the overmold used for the storage tubing
24 is in the same configuration as the Denali delivery system (Question 1). Ex. B, Van Vleet
25 Decl. at ¶ 33.

26 **Admit.**
27
28

1 586. Additionally, BPV provided FDA with a revised 510(k) summary to more
2 clearly describe the changes to the device, per FDA's request (Question 2). Ex. B, Van
3 Vleet Decl. at ¶ 33.

4 **Admit. FDA's request did not establish any *additional requirements* for**
5 **completing the 510(k) clearance process. The information requested was in response**
6 **to deficiencies in Bard's 510(k) submission.**

7 587. On October 24, 2011, FDA sent BPV a letter clearing the Meridian® Filter
8 System -- Femoral Delivery Kit (K112497). Ex. B, Van Vleet Decl. at ¶ 34.

9 **Admit.**

10 **VIII. Denali® Filter:**

11 588. As early as August 14, 2009, BPV began discussing with FDA BPV's plans
12 to develop the Denali® Filter (almost four years before FDA cleared the device). Ex. B,
13 Van Vleet Decl. at ¶ 35.

14 **Objection. This statement contains inadmissible hearsay and, in addition,**
15 **lacks foundation. Subject to said objections, admit that the relied upon document**
16 **references an August 14, 2009, meeting between Bard personnel and FDA**
17 **representative Angela Smith, and that the memo of the meeting contains a passing**
18 **reference to a "laser-cut filter with caudal anchors." The statements that this is a**
19 **reference to the Denali filter or that this constituted a "discussion with FDA" of**
20 **Bard's plans to develop the Denali filter are unsupported by any exhibit and are**
21 **denied.**

22 589. In BPV's discussion with FDA, BPV told FDA about BPV's planned
23 project for a "laser-cut filter with caudal anchors." This project eventually became the
24 Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 35.

25 **Objection. This statement contains inadmissible hearsay. Subject to said**
26 **objection, admit that the relied upon document references an August 14, 2009,**
27 **meeting between Bard personnel and FDA representative Angela Smith, and that the**
28 **memo of the meeting contains a passing reference to a "laser-cut filter with caudal**

1 **anchors.” The statements that this is a reference to the Denali filter or that this**
2 **constituted a “discussion with FDA” of Bard’s plans to develop the Denali filter are**
3 **unsupported by any exhibit and are denied.**

4 590. On March 19, 2010, BPV provided FDA with BPV’s Denali Pre-IDE
5 narrative, proposed animal protocol, and proposed clinical protocol summary. Ex. B, Van
6 Vleet Decl. at ¶ 36.

7 **Admit.**

8 591. The purpose of providing this information to FDA was to request the
9 agency’s feedback regarding the acceptability of BPV’s proposed pre-clinical and clinical
10 test studies in order to gain clearance for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶
11 36.

12 **Objection. This statement contains inadmissible hearsay. Subject to said**
13 **objection, deny. The referenced document does not support this characterization of**
14 **Bard’s purpose or intent for providing the documents to the FDA. This “fact” is**
15 **actually an opinion about why Bard was providing this information. Deny to the**
16 **extent it implies the FDA was asking for additional information.**

17 592. Accordingly, BPV provided FDA with a copy of the proposed GLP animal
18 study protocol, and described the proposed study for FDA. Ex. B, Van Vleet Decl. at ¶
19 36.

20 **Admit in part, deny in part. Admit the document lists “Denali animal protocol**
21 **– Appendix 1” and “Denali clinical protocol summary –Appendix 2” as attachments.**
22 **Deny to the extent it implies the FDA was asking for additional information.**

23 593. Additionally, BPV provided FDA with a copy of BPV’s proposed clinical
24 study protocol summary, and described the basic contours of BPV’s proposed study. Ex.
25 B, Van Vleet Decl. at ¶ 36.

26 **Admit in part, deny in part. Admit the document lists “Denali animal protocol**
27 **– Appendix 1” and “Denali clinical protocol summary –Appendix 2” as attachments.**
28 **Deny to the extent it implies the FDA was asking for additional information.**

1 594. On May 5, 2010, in advance of a face-to-face meeting with FDA, BPV
2 provided the agency with PowerPoint slides that BPV intended to show FDA at the
3 meeting. Ex. B, Van Vleet Decl. at ¶ 37.

4 **Admit.**

5 595. These slides identified the objective of the meeting, which was to obtain
6 FDA's feedback on the acceptability of the proposed bench studies, animal study, and
7 clinical protocol summary that BPV intended to conduct for the Denali® Filter. Ex. B,
8 Van Vleet Decl. at ¶ 37.

9 **Admit.**

10 596. In the presentation, BPV described the battery of *in-vitro* bench tests it
11 proposed to conduct. Ex. B, Van Vleet Decl. at ¶ 37.

12 **Admit in part, deny in part. Admit that in the referenced PowerPoint**
13 **presentation document there is a list of the proposed bench testing and a brief one**
14 **sentence description of Bard's "risk mitigation explanation." Deny to the extent**
15 **Bard implies that it described the specifics of the proposed testing.**

16 597. BPV also described the proposed *in-vivo* animal study and clinical study
17 that BPV proposed to conduct. Ex. B, Van Vleet Decl. at ¶ 37.

18 **Admit in part, deny in part. Admit that within the referenced PowerPoint**
19 **presentation document is a graph titled "in-vivo GLP Animal Study." Deny to the**
20 **extent Bard implies that it described the specifics of the proposed study.**

21 598. Finally, BPV explained its proposed regulatory strategy of gaining 510(k)
22 clearance for Denali® as a permanent filter, with the proposed clinical study supporting a
23 retrievable indication. Ex. B, Van Vleet Decl. at ¶ 37.

24 **Objection. This statement contains inadmissible hearsay. Subject to said**
25 **objection, admit that within the referenced PowerPoint presentation document is a**
26 **chart titled "Denali Submission Strategy." Deny to the extent Bard implies that it**
27 **described their strategy to the FDA.**
28

1 599. On May 5, 2010, BPV and FDA had a face-to-face meeting to discuss
2 BPV's Pre-IDE submission, proposed animal and clinical studies, and regulatory strategy
3 for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 38.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit that the relied upon document references an May 15, 2010, meeting**
6 **between Bard personnel and FDA personnel in which clinical data for the**
7 **permanent indication of the Bard Denali filter was discussed. Deny all other**
8 **assertions and characterizations to extent they imply the FDA was requiring**
9 ***additional information* above and beyond the requirements of the 510(k) clearance**
10 **process.**

11 600. During the meeting, FDA provided feedback regarding BPV's proposed *in-*
12 *vivo* animal study. Ex. B, Van Vleet Decl. at ¶ 38.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit in part, deny in part. Admit that the relied-upon document**
15 **describes a discussion by FDA personnel of animal studies. Deny all other assertions**
16 **and characterizations to extent they imply the FDA was requiring *additional***
17 ***information* beyond the requirements of the 510(k) clearance process.**

18 601. In particular, FDA stated that BPV would need a veterinarian to observe the
19 animals daily for three days following the operation, instead of having a veterinarian
20 review records via email or fax. Ex. B, Van Vleet Decl. at ¶ 38.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, admit that the relied-upon document describes a discussion with FDA**
23 **personnel about veterinarian participation in Bard's proposed animal study. Deny**
24 **all other assertions and characterizations to extent they imply the FDA was**
25 **requiring *additional information* beyond the requirements of the 510(k) clearance**
26 **process.**

1 602. Regarding BPV’s proposed clinical study, FDA stated that “safety and
2 effectiveness data is needed to measure the permanent placement of filters.” Ex. B, Van
3 Vleet Decl. at ¶ 38.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit in part, deny in part. Admit that the relied-upon document is**
6 **quoted accurately. Deny all other assertions and characterizations to extent they**
7 **imply the FDA was requiring *additional information* beyond the requirements of the**
8 **510(k) clearance process. Deny FDA’s review was for independent establishment of**
9 **safety and effectiveness specific to the Denali filter; the review was for substantial**
10 **equivalence to the predicate. Ex. 3 at ¶¶ 25 -26.**

11 603. Given the design differences between the Denali® Filter and its predicate
12 device (the Eclipse® Filter), FDA was going to “require a Traditional 510(k).” Ex. B,
13 Van Vleet Decl. at ¶ 38.

14 **Objection. This statement contains inadmissible hearsay. Subject to said**
15 **objection, admit that the relied-upon document is quoted accurately. Deny all other**
16 **assertions and characterizations to extent they imply the FDA was requiring**
17 ***additional information* beyond the requirements of the 510(k) clearance process.**
18 **Specifically, the FDA is expressing their requests as what they were or were not**
19 **“comfortable” with.**

20 604. FDA further stated that “FDA is not comfortable having no clinical data to
21 support the permanent indication.” Ex. B, Van Vleet Decl. at ¶ 38.

22 **Objection. This statement contains inadmissible hearsay. Subject to said**
23 **objection, admit that the relied-upon document is quoted accurately. Deny all other**
24 **assertions and characterizations to extent they imply the FDA was requiring**
25 ***additional information* beyond the requirements of the 510(k) clearance process.**

26 605. Accordingly, FDA advised that it “would talk further following the pre-IDE
27 meeting and provide Bard with a recommendation on if clinical data would be required for
28 the permanent indication.” Ex. B, Van Vleet Decl. at ¶ 38.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the relied-upon document is quoted accurately. Deny all other assertions and characterizations to extent they imply the FDA was requiring additional information beyond the requirements of the 510(k) clearance process.

606. On May 13, 2010, FDA sent BPV an email following up on the May 5, 2010 meeting. Ex. B, Van Vleet Decl. at ¶ 39.

Admit.

607. In FDA's email to BPV, the agency expressed its conclusion that a pre-market clinical trial would be required before FDA would clear Denali® Filter, even for a permanent indication. Ex. B, Van Vleet Decl. at ¶ 39.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit the FDA stated in their email to Bard "we feel clinical data would be necessary to support permanent indication."

608. Specifically, FDA stated as follows: "I also wanted to let you know that the review team internally discussed the issue of clinical data for the permanent indication of the Bard Denali Filter. We understand that historically, clinical data was not always necessary to support a permanent indication for Bard IVC filters. However, because of the significant design changes to your device, the length of time that has elapsed since the last clinical study involving Bard filters, and the recently-identified clinical risks associated with IVC filters in general, we feel that clinical data would be necessary to support a permanent indication. This position is consistent with recommendations we would give any other sponsor in the same position." Ex. B, Van Vleet Decl. at ¶ 39.

Admit that the statement of fact accurately quotes the subject document.

609. In FDA's email to BPV, the agency also included its own meeting minutes from the May 5, 2010 meeting. Ex. B, Van Vleet Decl. at ¶ 39.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the subject document includes what the document describes as FDA's official meeting minutes. But this statement is misleading and lacks context;

1 the FDA's minutes were a nearly verbatim copy of the meeting memo that Bard had
2 prepared.

3 610. Those minutes confirmed FDA's requirement that BPV submit a Traditional
4 510(k) for the Denali® Filter, and that BPV would need a veterinarian to observe the
5 animals daily for three days following the operation, instead of having a veterinarian
6 review records via email or fax.

7 **Objection. This statement contains inadmissible hearsay. Subject to said**
8 **objection, admit that the subject document includes what the document describes as**
9 **FDA's official meeting minutes. Deny all other assertions and characterizations to**
10 **extent they imply the FDA was requiring *additional information* beyond the**
11 **requirements of the 510(k) clearance process. This statement and Bard's**
12 **characterization of the meeting minutes are misleading and lack context; the FDA's**
13 **minutes were a nearly verbatim copy of the meeting memo that Bard prepared.**

14 611. On May 20, 2010, FDA and BPV had a follow-up teleconference regarding
15 the May 5, 2010 meeting and FDA's opinion that BPV would be required to conduct a
16 pre-market clinical study to gain clearance of the Denali® Filter. Ex. B, Van Vleet Decl.
17 at ¶ 40.

18 **Objection. This statement contains inadmissible hearsay. Subject to said**
19 **objection, admit in part, deny in part. Admit that the relied upon document**
20 **references a May 20, 2010, telephone call between Bard personnel and FDA**
21 **personnel in which the May 5, 2010, meeting and other regulatory issues regarding**
22 **Bard's IVC filters were discussed. Deny all other assertions and characterizations to**
23 **extent they imply the FDA was requiring *additional information* beyond the**
24 **requirements of the 510(k) clearance process. This document demonstrates that the**
25 **FDA infers that "this recommendation would be consistent across all sponsors."**

26 612. FDA stated that its decision to require pre-market clinical data was based on
27 "the increasing literature and clinical practice uncovering filter complications and new
28 risks." Ex. B, Van Vleet Decl. at ¶ 40.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit in part, deny in part. Admit that the subject document is accurately quoted. Deny all other assertions and characterizations to extent they imply the FDA was requiring *additional information* beyond the requirements of the 510(k) clearance process.

613. On June 7, 2010, FDA and BPV had a follow-up teleconference to discuss the Denali® clinical trial endpoints and regulatory strategy for the device. Ex. B, Van Vleet Decl. at ¶ 41.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit in part, deny in part. Admit that the relied-upon document references a June 7, 2010, telephone call between Bard personnel and FDA personnel in which the May 5, 2010, meeting and other regulatory issues were regarding Bard's IVC filters were discussed. Deny all other assertions and characterizations to extent they imply the FDA was requiring *additional information* beyond the requirements of the 510(k) clearance process.

614. During the meeting, BPV discussed its proposed permanent and retrievable endpoints and submission strategy. Ex. B, Van Vleet Decl. at ¶ 41.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the relied-upon document contains statements of this nature.

615. In response to BPV's proposal, FDA stated it wanted Bard's protocol to include complications with a "comparison to SIR guidelines." Ex. B, Van Vleet Decl. at ¶ 41.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the subject document is accurately quoted. Deny all other assertions and characterizations to extent they imply the FDA proposed Bard's use of the SIR guidelines. Bard initially discussed their proposed study endpoints "as described by SIR guidelines" and according to this document FDA responded by

1 **stating “this would be acceptable” and then suggested there “should be a comparison**
 2 **to the guidelines.”**

3 616. FDA then stated it would accept a Traditional 510(k) for Denali® Filter for
 4 permanent and retrievable indication once the clinical trial reached 100 subjects being
 5 followed to 6 months post-implant and 45 removals. Ex. B, Van Vleet Decl. at ¶ 41.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
 7 **objection, admit.**

8 617. On December 10, 2010, BPV sent FDA an email again confirming BPV’s
 9 submission plan for the Denali IDE and subsequent 510(k) submission. Ex. B, Van Vleet
 10 Decl. at ¶ 42.

11 **Admit in part, deny in part. Admit Bard sent an email to the FDA with their**
 12 **submission plan for the Denali IDE and their 510(k) submission. Deny that Bard sent**
 13 **this email “again.”**

14 618. BPV confirmed its plan to submit an IDE for approval, and following IDE
 15 approval, to submit a Traditional 510(k) for permanent and retrievable indication once the
 16 clinical trial reached 100 subjects having been followed for 6 months post-implant and the
 17 completion of 45 filter retrievals. Ex. B, Van Vleet Decl. at ¶ 42.

18 **Admit in part, deny in part. Admit Bard sent an email to the FDA seeking**
 19 **confirmation that their submission plan was acceptable for the Denali IDE and the**
 20 **Denali 510(k). Deny this email “confirmed” Bard’s submission plan with the FDA.**

21 619. BPV also confirmed it would continue following subjects through 24
 22 months. Ex. B, Van Vleet Decl. at ¶ 42.

23 **Admit in part, deny in part. Admit Bard sent an email to the FDA seeking**
 24 **confirmation that their submission plan was acceptable for the Denali IDE and the**
 25 **Denali 510(k). Deny this email “confirmed” Bard’s submission plan with the FDA.**

26 620. On December 30, 2010, BPV submitted its IDE application for the Denali®
 27 Filter to the FDA. Ex. B, Van Vleet Decl. at ¶ 43.

28 **Admit.**

1 621. This IDE application included all of the required elements for an IDE
2 application under §812.20(b), including the clinical protocol for the study, which
3 identified all primary and secondary endpoints. Ex. B, Van Vleet Decl. at ¶ 43.

4 **Objection. This statement lacks foundation, and is a legal conclusion rather**
5 **than a statement of fact. Subject to said objections, deny. 21 C.F.R. § 812.20 does**
6 **not include clinical protocols for studies done pursuant to an IDE nor study**
7 **endpoints. These details and the study specifics are left to the sponsor seeking an**
8 **IDE. See 21 C.F.R. § 812.20.**

9 622. This application included a summary description and data sheets for the
10 battery of *in-vitro* and *in-vivo* tests conducted on the Denali® Filter, including respiratory
11 fatigue resistance and corrosion evaluation, diaphragmatic fatigue resistance and corrosion
12 evaluation, corrosion resistance (fatigue and non-fatigued filters), cranial migration
13 resistance, caudal migration resistance, radial force, tensile strength (arm, leg, penetration
14 limiter & snare tip), removal force, clot trapping efficiency, filter tip visibility
15 (radiopacity), and MRI compatibility. Ex. B, Van Vleet Decl. at ¶ 43.

16 **Admit.**

17 623. BPV also included a summary of its *in-vivo* animal studies. Ex. B, Van
18 Vleet Decl. at ¶ 43.

19 **Admit.**

20 624. BPV also included in its IDE application the Denali® Filter design failure
21 mode and effect analysis (“DFMEA”), bench test protocols & reports (including MRI and
22 corrosion), stability protocol summary, biocompatibility reports, ethylene oxide &
23 chlorhydrin test report, endotoxin test report, and animal study reports. Ex. B, Van Vleet
24 Decl. at ¶ 43.

25 **Admit.**

26 625. On February 2, 2011, FDA sent BPV a letter conditionally approving BPV’s
27 IDE (G110001) for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 44.

1 **Subject to the clarification that it was Bard’s IDE *application* that was**
 2 **approved, admit.**

3 626. FDA’s approval of BPV’s IDE for the Denali® Filter was granted on the
 4 “condition that . . . [BPV] submit information correcting” 31 deficiencies identified by
 5 FDA in its letter. Ex. B, Van Vleet Decl. at ¶ 44.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
 7 **objection, and subject to the clarification that it was Bard’s IDE *application* that was**
 8 **approved, admit FDA granted approval of Bard’ Denali IDE application conditioned**
 9 **on the correction of thirty one (31) deficiencies.**

10 627. The first 13 questions identified by FDA concerned clinical aspects of
 11 BPV’s proposed trial. Ex. B, Van Vleet Decl. at ¶ 44.

12 **Admit.**

13 628. In particular, FDA directed BPV to make various changes and revisions to
 14 BPV’s informed consent document (Questions 1a-1f). Ex. B, Van Vleet Decl. at ¶ 44.

15 **Objection. This statement contains inadmissible hearsay. Subject to said**
 16 **objection, admit that the relied-upon document describes a discussion by FDA**
 17 **personnel of the Informed Consent document included with Bard’s IDE application.**
 18 **Admit the information requested was in response to deficiencies in Bard’s Denali**
 19 **IDE application.**

20 629. Additionally, FDA requested that BPV include a metric measurement to
 21 assess the primary endpoints of the study (Question 2). Ex. B, Van Vleet Decl. at ¶ 44.

22 **Objection. This statement contains inadmissible hearsay. Subject to said**
 23 **objection, admit that the relied-upon document describes a discussion by FDA**
 24 **personnel of the endpoints of the study included with Bard’s IDE application. The**
 25 **information requested was in response to deficiencies in Bard’s Denali IDE**
 26 **application. Deny all other assertions and characterizations to the extent they imply**
 27 **that the FDA’s request established any *additional requirements* for Bard’s Denali**
 28 **IDE application.**

1 630. FDA also required that BPV add deep vein thrombosis (“DVT”) as a
2 secondary endpoint (Question 3), and to propose a time frame to evaluate secondary
3 endpoints (Question 4). Ex. B, Van Vleet Decl. at ¶ 44.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit that the relied-upon document describes a discussion by FDA**
6 **personnel of the endpoints of the study included with Bard’s IDE application. The**
7 **information requested was in response to deficiencies in Bard’s Denali IDE**
8 **application. Deny all other assertions and characterizations to the extent they imply**
9 **that the FDA’s request established any *additional requirements* for Bard’s Denali**
10 **IDE application.**

11 631. FDA also requested that BPV make certain changes to the inclusion and
12 exclusion criteria for study subjects and for exclusion criteria for retrievals (Questions 5-
13 7). Ex. B, Van Vleet Decl. at ¶ 44.

14 **Objection. This statement contains inadmissible hearsay. Subject to said**
15 **objection, admit that the relied-upon document describes a discussion by FDA**
16 **personnel of the details of the study included with Bard’s IDE application. Deny all**
17 **other assertions and characterizations. The information requested was in response**
18 **to deficiencies in Bard’s Denali IDE application. Deny all other assertions and**
19 **characterizations to the extent they imply that the FDA’s request established any**
20 ***additional requirements* for Bard’s Denali IDE application.**

21 632. FDA also required that BPV revise the list of assessments and tests for study
22 subjects to include physical examination and Doppler ultrasound at enrollment and at 6
23 months (Question 9). Ex. B, Van Vleet Decl. at ¶ 44.

24 **Objection. This statement contains inadmissible hearsay. Subject to said**
25 **objection, admit that the relied-upon document describes a discussion by FDA**
26 **personnel of the details of the study included with Bard’s IDE application. The**
27 **information requested was in response to deficiencies in Bard’s Denali IDE**
28 **application. Deny all other assertions and characterizations to the extent they imply**

1 **that the FDA's request established any *additional requirements* for Bard's Denali**
2 **IDE application.**

3 633. FDA also requested that BPV identify a Data Safety Monitoring Board
4 (DSMB) to monitor the safety of the device during the clinical trial (Question 10). Ex. B,
5 Van Vleet Decl. at ¶ 44.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
7 **objection, admit that the relied-upon document describes a discussion by FDA**
8 **personnel of the details of the study included with Bard's IDE application. The**
9 **information requested was in response to deficiencies in Bard's Denali IDE**
10 **application. Deny all other assertions and characterizations to the extent they imply**
11 **that the FDA's request established any *additional requirements* for Bard's Denali**
12 **IDE application.**

13 634. Finally, FDA directed that BPV make changes to the clinical protocol to add
14 a description of the intended use of the Denali® Filter (Question 11), and to describe
15 when the secondary endpoint of penetration/perforation will be assessed (Question 13).
16 FDA also asked for certain changes to the Case Report Forms (Question 12). Ex. B, Van
17 Vleet Decl. at ¶ 44.

18 **Objection. This statement contains inadmissible hearsay. Subject to said**
19 **objection, admit that the relied-upon document describes a discussion by FDA**
20 **personnel of the details of the study included with Bard's IDE application. The**
21 **information requested was in response to deficiencies in Bard's Denali IDE**
22 **application. Deny all other assertions and characterizations to the extent they imply**
23 **that the FDA's request established any *additional requirements* for Bard's Denali**
24 **IDE application.**

25 635. The remaining 17 questions addressed non-clinical issues associated with
26 the *in-vivo* animal testing for the Denali® Filter and with the *in-vitro* bench testing for the
27 Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 44.
28

1 **Objection. This statement contains inadmissible hearsay. Subject to said**
 2 **objection, admit.**

3 636. In particular, FDA required BPV to conduct additional testing before FDA
 4 would finally approve the Denali® Filter IDE. Ex. B, Van Vleet Decl. at ¶ 44.

5 **Objection. This statement contains inadmissible hearsay, and is misleading in**
 6 **the use of the words “required” and “additional.” Subject to said objections, admit**
 7 **that the relied-upon document describes a discussion by FDA personnel of the details**
 8 **of the studies included with Bard’s IDE application and made reference to an**
 9 **additional clot trap study. The information requested was in response to deficiencies**
 10 **in Bard’s Denali IDE application. Deny that the FDA required specific tests. See Ex.**
 11 **5 at 51:15-17. Deny all other assertions and characterizations to the extent they**
 12 **imply that the FDA’s request established any *additional requirements* for Bard’s**
 13 **Denali IDE application.**

14 637. Specifically, FDA required BPV to conduct additional clot trapping
 15 efficiency testing using a “shower of clots of multiple sizes” (Question 23). Ex. B, Van
 16 Vleet Decl. at ¶ 44.

17 **Objection. This statement contains inadmissible hearsay, and is misleading in**
 18 **the use of the words “required” and “additional.” Subject to said objections, admit**
 19 **that the relied-upon document describes a discussion by FDA personnel of the details**
 20 **of the studies included with Bard’s IDE application and made reference to an**
 21 **additional clot trap study. The information requested was in response to deficiencies**
 22 **in Bard’s Denali IDE application. Deny that the FDA required specific tests. See Ex.**
 23 **5 at 51:15-17. Deny all other assertions and characterizations to the extent they**
 24 **imply that the FDA’s request established any *additional requirements* for Bard’s**
 25 **Denali IDE application.**

26 638. FDA also required BPV to conduct shelf-life testing (stability) for radial
 27 strength, tensile strength, and delivery system torque (Question 25). Ex. B, Van Vleet
 28 Decl. at ¶ 44.

1 **Objection.** This statement contains inadmissible hearsay, and is misleading in
 2 the use of the word “required.” Subject to said objections, admit that the relied-
 3 upon document describes a discussion by FDA personnel of the details of the studies
 4 included with Bard’s IDE application. The information requested was in response to
 5 deficiencies in Bard’s Denali IDE application. Deny that the FDA required specific
 6 tests. *See Ex. 5 at 51:15-17.* Deny all other assertions and characterizations to the
 7 extent they imply that the FDA’s request established any *additional requirements* for
 8 Bard’s Denali IDE application.

9 639. FDA also required BPV to conduct certain additional biocompatibility
 10 testing and analyses for the Denali® Filter (Questions 27, 30, 31). Ex. B, Van Vleet Decl.
 11 at ¶ 44.

12 **Objection.** This statement contains inadmissible hearsay, and is misleading in
 13 the use of the words “required” and “additional.” Subject to said objections, admit
 14 that the relied-upon document describes a discussion by FDA personnel of the details
 15 of the studies included with Bard’s IDE application including references to
 16 additional follow-up testing. The information requested was in response to
 17 deficiencies in Bard’s Denali IDE application. Deny that the FDA required specific
 18 tests. *See Ex. 5 at 51:15-17.* Deny all other assertions and characterizations to the
 19 extent they imply that the FDA’s request established any *additional requirements* for
 20 Bard’s Denali IDE application.

21 640. FDA also required BPV to make a revision to the Denali® Filter labeling
 22 before FDA would finally approve the Denali® Filter IDE. The change involved adding
 23 language regarding MRI labeling (Question 26b). Ex. B, Van Vleet Decl. at ¶ 44.

24 **Objection.** This statement contains inadmissible hearsay, and is misleading in
 25 the use of the word “required.” Subject to said objections, admit that the relied-
 26 upon document describes a discussion by FDA personnel of the details of the MRI
 27 labeling. Deny all other assertions and characterizations to the extent they imply this
 28 was mandatory or “required.” Labeling revisions and changes are negotiated

1 between the FDA and a manufacturer, not required. *See* Ex. 11 at 92:1-4. The FDA
2 referenced an FDA guidance document which “*recommends* the following” language
3 to be used (emphasis added). This statement mischaracterizes and takes FDA’s
4 statements in the letter out of context to imply that the discussion in the letter
5 imposed mandatory requirements on Bard.

6 641. FDA also requested specific information concerning how deformation
7 values for fatigue testing were derived from literature (Question 18). Ex. B, Van Vleet
8 Decl. at ¶ 44.

9 **Objection.** This statement contains inadmissible hearsay. Subject to said
10 objection, admit that the relied-upon document describes a discussion by FDA
11 personnel of the literature regarding fatigue testing. The information requested was
12 in response to deficiencies in Bard’s Denali IDE application. Deny that the FDA
13 required specific tests. *See* Ex. 5 at 51:15-17. Deny all other assertions and
14 characterizations to the extent they imply that the FDA’s request established any
15 *additional requirements* for Bard’s Denali IDE application.

16 642. FDA also requested information regarding the mock vessel used for
17 migration resistance testing and an explanation for how this material is similar to or
18 different from native IVC tissue (Question 21a). Ex. B, Van Vleet Decl. at ¶ 44.

19 **Objection.** This statement contains inadmissible hearsay, and is misleading in
20 the use of the words “required” and “additional.” Subject to said objections, admit
21 that the relied-upon document describes a discussion by FDA personnel of the details
22 of the studies included with Bard’s IDE application including references to
23 additional follow-up testing. The information requested was in response to
24 deficiencies in Bard’s Denali IDE application. Deny that the FDA required specific
25 tests. *See* Ex. 5 at 51:15-17. Deny all other assertions and characterizations to the
26 extent they imply that the FDA’s request established any *additional requirements* for
27 Bard’s Denali IDE application.
28

1 643. FDA also requested justification for BPV's radial force acceptance criteria
2 (Question 22). Ex. B, Van Vleet Decl. at ¶ 44.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
4 **objection, admit that the relied-upon document describes a discussion by FDA**
5 **personnel of Bard's criteria for radial force testing. The information requested was**
6 **in response to deficiencies in Bard's Denali IDE application. Deny all other**
7 **assertions and characterizations to the extent they imply that the FDA's request**
8 **established any *additional requirements* for Bard's Denali IDE application.**

9 644. FDA also directed BPV to provide the agency with various additional
10 information concerning the *in-vivo* animal studies for the Denali® Filter (Questions 14-
11 16). Ex. B, Van Vleet Decl. at ¶ 44.

12 **Objection. This statement contains inadmissible hearsay, and is misleading in**
13 **the use of the word "additional." Subject to said objections, admit that the relied-**
14 **upon document describes a discussion by FDA personnel of Bard's animal studies.**
15 **The information requested was in response to deficiencies in Bard's Denali IDE**
16 **application. Deny that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny**
17 **all other assertions and characterizations to the extent they imply that the FDA's**
18 **request established any *additional requirements* for Bard's Denali IDE application.**

19 645. FDA also asked for various test reports, data sheets, and other information,
20 including data sheets for the jugular/subclavian delivery systems (Question 17), images of
21 post-fatigued devices (Question 19), clarification regarding the definition of filter
22 detachment (Question 20), clarification regarding units used for tensile testing (Question
23 24), and data showing how BPV's computational results were experimentally validated
24 (Question 26a). Ex. B, Van Vleet Decl. at ¶ 44.

25 **Objection. This statement contains inadmissible hearsay. Subject to said**
26 **objection that the relied-upon document describes a discussion by FDA personnel of**
27 **the details of the studies included with Bard's IDE application including references**
28 **to additional follow-up testing. The information requested was in response to**

1 **deficiencies in Bard's Denali IDE application. Deny that the FDA required specific**
2 **tests. See Ex. 5 at 51:15-17. Deny all other assertions and characterizations to the**
3 **extent they imply that the FDA's request established any *additional requirements* for**
4 **Bard's Denali IDE application.**

5 646. On February 10, 2011, FDA and BPV had a teleconference to discuss the
6 clinical deficiencies (Question 1-13) identified by FDA in its conditional IDE approval
7 letter of February 2, 2011. Ex. B, Van Vleet Decl. at ¶ 45.

8 **Objection. This statement contains inadmissible hearsay. Subject to said**
9 **objection, admit that the relied-upon document references a February 10, 2011,**
10 **telephone call between Bard personnel and FDA personnel in which deficiencies in**
11 **Bard's Denali IDE application were discussed.**

12 647. During the teleconference, FDA indicated it would accept BPV's proposed
13 metric measurement (proposed in response to Question 2) with a one-sided lower-limit of
14 the 95% confidence interval for the observed clinical success rate of greater than or equal
15 to 80%. Ex. B, Van Vleet Decl. at ¶ 45.

16 **Objection. This statement contains inadmissible hearsay. Subject to said**
17 **objection, admit that the relied-upon document describes a discussion by FDA**
18 **personnel of metric measurements for Bard's clinical protocol. The information was**
19 **initially requested was in response to deficiencies in Bard's Denali IDE application.**
20 **Deny all other assertions and characterizations. It is unclear whether this was**
21 **accepted at face value by the FDA, whether other metrics considered, or what the**
22 **FDA's position truly was.**

23 648. BPV indicated that the rate was based on a combined total of 20% for the
24 complication thresholds suggested by SIR and implemented in the Option Vena Cava
25 Filter prospective study for the following elements that make up clinical failure: technical
26 failure, subsequent PE, caval occlusion, filter embolization, death, and insertion site
27 adverse events. Ex. B, Van Vleet Decl. at ¶ 45.

1 **Objection. This statement contains inadmissible hearsay. Subject to said**
2 **objection, admit that the relied-upon document describes a discussion by FDA**
3 **personnel of metric measurements for Bard's clinical protocol. The information was**
4 **initially requested was in response to deficiencies in Bard's Denali IDE application.**
5 **Deny all other assertions and characterizations. It is unclear whether this was**
6 **accepted at face value by the FDA, whether other metrics considered, or what the**
7 **FDA's position truly was.**

8 649. BPV and FDA also discussed the company's proposed responses to the
9 remaining clinical deficiencies identified in FDA's letter (Questions 1, 3-13), including
10 increasing the number of permanent patients (100) reaching 6 months post-placement and
11 retrieval patients (50) before it would be appropriate for BPV to submit a Traditional
12 510(k) for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 45.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit that the relied-upon document describes a discussion by FDA**
15 **personnel of the clinical deficiencies for Bard's Denali IDE application. The**
16 **information was initially requested was in response to deficiencies in Bard's Denali**
17 **IDE application. Deny all other assertions and characterizations. It is unclear**
18 **whether this was accepted at face value by the FDA, whether other metrics**
19 **considered, or what the FDA's position truly was.**

20 650. On February 16, 2011, BPV submitted its first IDE Supplement
21 (G11001/S001), which addressed the clinical deficiencies (Questions 1-13) from FDA's
22 February 1, 2011 Letter. Ex. B, Van Vleet Decl. at ¶ 46.

23 **Admit.**

24 651. In the first IDE Supplement, BPV made various changes and revisions to
25 BPV's informed consent document as requested by FDA (Questions 1a-1f). Ex. B, Van
26 Vleet Decl. at ¶ 46.

27 **Admit.**
28

1 652. As agreed to during the February 10, 2011 teleconference, BPV included a
2 metric measurement to assess the primary endpoints of the study (Question 2). Ex. B,
3 Van Vleet Decl. at ¶ 46.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit that the relied-upon document includes Bard's memo of the**
6 **conference call with the FDA which describes a discussion by FDA personnel of**
7 **metric measurements for Bard's clinical protocol. The information was initially**
8 **requested was in response to deficiencies in Bard's Denali IDE application. Deny all**
9 **other assertions and characterizations. It is also unclear whether this was accepted**
10 **at face value by the FDA, whether other metrics considered, or what the FDA's**
11 **position truly was.**

12 653. As approved by the agency, this metric measurement was a one-sided lower-
13 limit of the 95% confidence interval for the observed clinical success rate of greater than
14 or equal to 80%. Ex. B, Van Vleet Decl. at ¶ 46.

15 **Objection. This statement contains inadmissible hearsay. Subject to said**
16 **objection, admit that the relied-upon document includes Bard's memo of the**
17 **conference call with the FDA which describes a discussion by FDA personnel of**
18 **metric measurements for Bard's clinical protocol. The information was initially**
19 **requested was in response to deficiencies in Bard's Denali IDE application. Deny all**
20 **other assertions and characterizations. It is also unclear whether this was accepted**
21 **at face value by the FDA, whether other metrics considered, or what the FDA's**
22 **position truly was.**

23 654. As FDA required, BPV added DVT as a secondary endpoint (Question 3),
24 and proposed a time frame to evaluate secondary endpoints (Question 4). Ex. B, Van
25 Vleet Decl. at ¶ 46.

26 **Objection. This statement contains inadmissible hearsay and is misleading as**
27 **to the word "required."** Subject to these objections, admit that the relied-upon
28 **document includes Bard's memo of the conference call with the FDA which describes**

1 a discussion by FDA personnel of the endpoints for Bard's clinical study. Deny all
2 other assertions and characterizations to the extent they imply that the FDA's
3 request established any *additional requirements* for Bard's Denali IDE application.

4 655. Additionally, BPV also made the requested changes to the inclusion and
5 exclusion criteria for study subjects and to the exclusion criteria for retrievals, as FDA
6 requested (Questions 5-7). Ex. B, Van Vleet Decl. at ¶ 46.

7 **Objection.** This statement contains inadmissible hearsay. Subject to said
8 objection, admit that the relied-upon document includes Bard's memo of the
9 conference call with the FDA which describes a discussion by FDA personnel of the
10 details of Bard's clinical study. The information requested was in response to
11 deficiencies in Bard's Denali IDE application. Deny all other assertions and
12 characterizations to the extent they imply that the FDA's request established any
13 *additional requirements* for Bard's Denali IDE application.

14 656. BPV also revised the list of assessments and tests for study subjects to
15 include physical examination and Doppler ultrasound at enrollment and at 6 months per
16 FDA's request (Question 9). Ex. B, Van Vleet Decl. at ¶ 46.

17 **Objection.** This statement contains inadmissible hearsay. Subject to said
18 objection, admit that the relied-upon document includes Bard's memo of the
19 conference call with the FDA which describes a discussion by FDA personnel of the
20 details of Bard's clinical study. The information requested was in response to
21 deficiencies in Bard's Denali IDE application. Deny that the FDA required specific
22 tests. *See Ex. 5 at 51:15-17.* Deny all other assertions and characterizations to the
23 extent they imply that the FDA's request established any *additional requirements* for
24 Bard's Denali IDE application.

25 657. As FDA required, BPV revised the clinical protocol to identify a Data
26 Safety Monitoring Board (DSMB) to monitor the safety of the device during the clinical
27 trial (Question 10). Ex. B, Van Vleet Decl. at ¶ 46.

1 **Objection. This statement contains inadmissible hearsay, and is misleading in**
2 **the use of the word “required.” Subject to said objections, admit that the relied-upon**
3 **document includes Bard’s memo of the conference call with the FDA which describes**
4 **a discussion by FDA personnel of the details of Bard’s clinical study. Deny all other**
5 **assertions and characterizations to the extent they imply that the FDA’s request**
6 **established any *additional requirements* for Bard’s Denali IDE application. The**
7 **information requested was in response to deficiencies in Bard’s Denali IDE**
8 **application.**

9 658. BPV also made FDA’s other requested changes to the clinical protocol and
10 case report forms (Questions 11-13). Ex. B, Van Vleet Decl. at ¶ 46.

11 **Objection. This statement contains inadmissible hearsay. Subject to said**
12 **objection, admit that the relied-upon document includes Bard’s memo of the**
13 **conference call with the FDA which describes a discussion by FDA personnel of the**
14 **details of Bard’s clinical study. Deny all other assertions and characterizations. The**
15 **information requested was in response to deficiencies in Bard’s Denali IDE**
16 **application.**

17 659. BPV included with its first IDE Supplement the FDA meeting minutes from
18 February 10, 2011, revised and redlined informed consent forms, clinical protocol, and
19 case report forms, and the referenced publications from BPV’s Supplement. Ex. B, Van
20 Vleet Decl. at ¶ 46.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, deny that the relied-upon document includes “the FDA meeting minutes”**
23 **from the February 10, 2011, conference call. The summary of the meeting was a**
24 **Bard memo prepared by Bard employees. Otherwise admit. The information**
25 **requested was in response to deficiencies in Bard’s Denali IDE application.**

26 660. On February 22, 2011, BPV sent FDA an email seeking FDA’s feedback on
27 whether BPV’s proposed plan to address FDA’s biocompatibility-related questions
28

1 (Questions 27-31) from FDA's February 1, 2011 letter would be acceptable to the agency.
2 Ex. B, Van Vleet Decl. at ¶ 47.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
4 **objection, admit. The information requested was in response to deficiencies in Bard's**
5 **Denali IDE application.**

6 661. In response to FDA's Questions 27-31, BPV proposed conducting "full
7 biocompatibility testing" on the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 47.

8 **Admit. The information requested was in response to deficiencies in Bard's**
9 **Denali IDE application.**

10 662. Such testing would include the following tests: Sensitization – Kligman
11 Guinea Pig Maximization; Irritation - Intracutaneous Reactivity; Systemic Toxicity -
12 Acute Systemic Toxicity – Systemic Injection; Systemic Toxicity – Material Mediated
13 Pyrogenicity; Implantation - 2-week Intramuscular Implantation; ; Genotoxicity - Ames
14 Reverse Mutation Assay; Genotoxicity - Chromosomal Aberration Assay; Genotoxicity –
15 Rodent Bone Marrow Micronucleus Assay; Hemocompatibility – Hemolysis;
16 Hemocompatibility - Complement Activation; and Hemocompatibility - Prothrombin
17 Time Assay. Ex. B, Van Vleet Decl. at ¶ 47.

18 **Admit. The information requested was in response to deficiencies in Bard's**
19 **Denali IDE application.**

20 663. BPV also indicated that Hemocompatibility *in-vivo* thrombogenicity
21 biocompatibility testing had been assessed through the 12 week GLP animal study, which
22 demonstrated no thrombus formation. Ex. B, Van Vleet Decl. at ¶ 47.

23 **Objection. This statement contains inadmissible hearsay. Subject to said**
24 **objection, admit. The information requested was in response to deficiencies in Bard's**
25 **Denali IDE application.**

26 664. BPV also informed FDA that the company did not believe it needed to
27 perform subacute toxicity, subchronic toxicity, chronic toxicity, or carcinogenicity testing
28 due to the long history of Nitinol implants being biocompatible, and given that the Nitinol

1 used for Denali® conforms to the FDA recognized standard ASTM F2063-05. Ex. B,
2 Van Vleet Decl. at ¶ 47.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
4 **objection, admit.**

5 665. On March 11, 2011, BPV sent FDA an email with BPV's proposed
6 responses to FDA's questions number 18 and 24 (regarding fatigue testing and tensile
7 strength testing) from FDA's February 1, 2011 letter. Ex. B, Van Vleet Decl. at ¶ 48.

8 **Objection. This statement contains inadmissible hearsay. Subject to said**
9 **objection, admit.**

10 666. In response to FDA's question concerning how deformation values for
11 fatigue testing were derived from the scientific literature (Question 18), BPV responded
12 by stating that the Denali® Filter fatigue testing parameters for diaphragmatic fatigue
13 were derived from a study by Bjarnason evaluating *in vitro* metal fatigue testing of IVC
14 filters. Ex. B, Van Vleet Decl. at ¶ 48.

15 **Objection. This statement contains inadmissible hearsay. Subject to said**
16 **objection, admit. The information requested was in response to deficiencies in Bard's**
17 **Denali IDE application.**

18 667. BPV also explained how its deformation values compared to an article by
19 Murphy, which evaluated the wall motion and dynamic geometry of the IVC in response
20 to valsalva. Ex. B, Van Vleet Decl. at ¶ 48.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, admit. The information requested was in response to deficiencies in Bard's**
23 **Denali IDE application.**

24 668. In response to FDA's question regarding units used for tensile testing
25 (Question 24), BPV explained that the units used were representative of the final design to
26 be used in the clinical trial. Ex. B, Van Vleet Decl. at ¶ 48.

1 **Objection. This statement contains inadmissible hearsay. Subject to said**
2 **objection, admit. The information requested was in response to deficiencies in Bard’s**
3 **Denali IDE application.**

4 669. On March 16, 2011, FDA and BPV had a telephone call to discuss BPV’s
5 proposed plan to address FDA’s biocompatibility concerns (Questions 27-31 from FDA’s
6 February 1, 2011 letter). Ex. B, Van Vleet Decl. at ¶ 49.

7 **Objection. This statement contains inadmissible hearsay. Subject to said**
8 **objection, admit.**

9 670. During the call, FDA indicated that BPV’s proposed biocompatibility
10 testing plan was acceptable. Ex. B, Van Vleet Decl. at ¶ 49.

11 **Objection. This statement contains inadmissible hearsay. Subject to said**
12 **objection, admit that the relied-upon document discusses a call with the FDA which**
13 **describes a discussion by FDA personnel of the deficiencies in Bard’s IDE**
14 **submission. Deny all other assertions and characterizations. This is a Bard internal**
15 **discussion of the call authored by Bard employees. The information requested was in**
16 **response to deficiencies in Bard’s Denali IDE application.**

17 671. FDA indicated that given BPV’s decision to omit certain testing (subacute
18 toxicity, subchronic toxicity, chronic toxicity, or carcinogenicity testing), FDA would
19 require BPV to perform x-ray photoelectron spectroscopy (XPS) analysis to see if any
20 contaminants are left on the surface. Ex. B, Van Vleet Decl. at ¶ 49.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, admit that the relied-upon document discusses a call with the FDA which**
23 **describes a discussion by FDA personnel of the deficiencies in Bard’s IDE**
24 **submission. Deny all other assertions and characterizations. This is a Bard internal**
25 **discussion of the call authored by Bard employees. It is unclear whether FDA’s**
26 **discussion of changes to Bard’s IDE submission was a requirement, request, or**
27 **suggestion by the FDA. The information requested was in response to deficiencies in**
28 **Bard’s Denali IDE application.**

1 672. On March 17, 2011, FDA sent BPV a revised letter conditionally approving
2 BPV's IDE (G110001) for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 50.

3 **Admit.**

4 673. In its March 17, 2011 letter, FDA indicated that BPV had "adequately
5 addressed" deficiencies 1-13 identified in FDA's February 1, 2011 letter. Ex. B, Van
6 Vleet Decl. at ¶ 50.

7 **Objection. This statement contains inadmissible hearsay. Subject to said**
8 **objection, admit that the statement accurately quotes the relied-upon document.**
9 **Deny all other assertions and characterizations.**

10 674. FDA further reiterated that it was conditionally approving the Denali®
11 Filter IDE "on the condition that . . . [BPV] submit information correcting deficiencies 14-
12 31" from FDA's February 1, 2011 letter. Ex. B, Van Vleet Decl. at ¶ 50.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit that the statement accurately quotes the relied-upon document.**
15 **Deny all other assertions and characterizations.**

16 675. On March 21, 2011, FDA sent BPV an email indicating that BPV's
17 proposed responses (sent March 11, 2011) to questions 18 and 24 from the February 1,
18 2011 FDA letter were acceptable and answered the FDA's questions. Ex. B, Van Vleet
19 Decl. at ¶ 51.

20 **Objection. This statement contains inadmissible hearsay. Subject to said**
21 **objection, admit that the relied-upon document includes a discussion of Bard's**
22 **responses to the FDA's questions about Bard's IDE submission for the Denali filter.**
23 **Deny all other assertions and characterizations.**

24 676. On August 9, 2011, BPV submitted its fifth IDE Supplement
25 (G11001/S005), which addressed the non-clinical deficiencies (Questions 14-31) from
26 FDA's February 1, 2011 Letter, and which were restated in FDA's March 17, 2011 letter.
27 Ex. B, Van Vleet Decl. at ¶ 52.

28 **Admit.**

1 677. In response to FDA’s requirement to conduct additional clot trapping
2 efficiency testing (Question 23), BPV had performed additional testing using a shower of
3 clots of multiple sizes and provided FDA with the report for this testing. Ex. B, Van Vleet
4 Decl. at ¶ 52.

5 **Objection. This statement contains inadmissible hearsay, and is misleading in**
6 **the use of the words “requirement” and “additional.” Subject to said objections,**
7 **admit that the relied-upon document includes such testing. This statement**
8 **mischaracterizes and takes FDA’s discussions with Bard about its Denali IDE**
9 **submission out of context to imply that the FDA required specific tests. Deny that the**
10 **FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions and**
11 **characterizations to the extent they imply that the FDA’s request established any**
12 ***additional requirements* for Bard’s Denali IDE application. The information**
13 **requested was in response to deficiencies in Bard’s Denali IDE application.**

14 678. In response to FDA’s requirement to conduct additional shelf-life testing
15 (Question 25), BPV agreed to perform shelf-life testing (stability) for radial strength,
16 tensile strength, and delivery system torque. BPV provided FDA with the revised stability
17 protocol summary reflecting this additional testing to be performed. Ex. B, Van Vleet
18 Decl. at ¶ 52.

19 **Objection. This statement contains inadmissible hearsay, and is misleading in**
20 **the use of the words “requirement” and “additional.” Subject to said objections,**
21 **admit that the relied-upon document includes a discussion of such testing. This**
22 **statement mischaracterizes and takes FDA’s discussions with Bard about its Denali**
23 **IDE submission out of context to imply that the FDA required specific tests. Deny**
24 **that the FDA required specific tests. See Ex. 5 at 51:15-17. Deny all other assertions**
25 **and characterizations to the extent they imply that the FDA’s request established**
26 **any *additional requirements* for Bard’s Denali IDE application. The information**
27 **requested was in response to deficiencies in Bard’s Denali IDE application.**
28

1 679. As indicated above, and as already deemed acceptable by FDA, BPV agreed
2 to perform full biocompatibility testing and XPS analysis (Questions 27-31). Ex. B, Van
3 Vleet Decl. at ¶ 52.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit that the relied-upon document states that BPV performed the**
6 **agreed to biocompatibility tests and includes a discussion of such testing. However,**
7 **deny to the extent defendant is implying this testing imposed some additional**
8 **requirement on BPV. The documents states that this BPV agreed to conduct this**
9 **testing in response to biocompatibility deficiencies identified by the FDA. Deny all**
10 **other assertions and characterizations. This statement mischaracterizes and takes**
11 **FDA's discussions with Bard about its Denali IDE submission out of context to imply**
12 **that the FDA imposed a mandatory requirement on Bard.**

13 680. BPV provided FDA with test reports for this testing. Ex. B, Van Vleet Decl.
14 at ¶ 52.

15 **Objection. This statement contains inadmissible hearsay. Subject to said**
16 **objection, admit.**

17 681. In response to FDA's request to revise the Denali® labeling (Question 26b),
18 BPV provided FDA with revised labeling that included language regarding MRI labeling.
19 Ex. B, Van Vleet Decl. at ¶ 52.

20 **Objection. This statement contains inadmissible hearsay. Subject to said**
21 **objection, admit that the relied-upon document includes a discussion of labeling and**
22 **that BPV revised the label to include updated language regarding MRI labeling.**
23 **Deny all other assertions and characterizations to the extent BPV implies that this**
24 **was an additional obligation imposed on BPV that was more onerous or above and**
25 **beyond what would normally be required as part of the IDE submission process.**
26 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
27 **Denali IDE submission out of context to imply that the FDA imposed a mandatory**
28 **requirement on Bard.**

1 682. Regarding FDA's questions concerning migration resistance testing, BPV
2 provided information and an explanation regarding the mock vessel used for migration
3 resistance testing and provided an explanation for how this material is similar to or
4 different from native IVC tissue (Question 21a). Ex. B, Van Vleet Decl. at ¶ 52.

5 **Objection. This statement contains inadmissible hearsay. Subject to said**
6 **objection, admit that BPV provided this information, but, deny to the extent BPV**
7 **implies this was an additional obligation imposed on BPV that was more onerous or**
8 **above and beyond what would normally be required as part of the IDE submission**
9 **process and not something that it was required to provide as part of its original**
10 **submission and was deficient in doing so.**

11 683. BPV also provided FDA with an explanation for BPV's radial force
12 acceptance criteria (Question 22), which FDA requested. Ex. B, Van Vleet Decl. at ¶ 52.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit that BPV provided this information, but, deny to the extent BPV**
15 **implies this was an additional obligation imposed on BPV that was more onerous or**
16 **above and beyond what would normally be required as part of the IDE submission**
17 **process and not something that it was required to provide as part of its original**
18 **submission and was deficient in doing so.**

19 684. In response to FDA's directions (Questions 14-16), BPV provided FDA
20 with various additional information concerning the *in-vivo* animal testing (Appendices 2-
21 4). Ex. B, Van Vleet Decl. at ¶ 52.

22 **Objection. This statement contains inadmissible hearsay. Subject to said**
23 **objection, admit that the relied-upon document includes additional information**
24 **concerning *in vivo* animal testing. Deny all other assertions and characterizations to**
25 **the extent BPV implies this was an additional obligation imposed on BPV that was**
26 **more onerous or above and beyond what would normally be required as part of the**
27 **IDE submission process and not something that it was required to provide as part of**
28 **its original submission and was deficient in doing so. This statement**

1 **mischaracterizes and takes FDA’s discussions with Bard about its Denali IDE**
2 **submission out of context to imply that the FDA imposed a mandatory requirement**
3 **on Bard.**

4 685. Finally, BPV provided FDA with the various other test reports, data sheets,
5 and other information requested by FDA, including data sheets for the jugular/subclavian
6 delivery systems (Question 17), images of post-fatigued devices (Question 19),
7 clarification regarding the definition of filter detachment (Question 20), clarification
8 regarding units used for tensile testing (Question 24), and data showing how BPV’s
9 computational results were experimentally validated (Question 26a). Ex. B, Van Vleet
10 Decl. at ¶ 52.

11 **Objection. This statement contains inadmissible hearsay. Subject to said**
12 **objection, admit that BPV provided this information, but, deny to the extent BPV**
13 **implies this was an additional obligation imposed on BPV that was more onerous or**
14 **above and beyond what would normally be required as part of the IDE submission**
15 **process and not something that it was required to provide as part of its original**
16 **submission and was deficient in doing so.**

17 686. On September 9, 2011, FDA sent BPV a further revised letter conditionally
18 approving BPV’s IDE (G110001) for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 53.

19 **Admit.**

20 687. FDA further reiterated that it was conditionally approving the Denali®
21 Filter IDE “on the condition that . . . [BPV] submit information correcting” 2 enumerated
22 deficiencies. Ex. B, Van Vleet Decl. at ¶ 53.

23 **Objection. This statement contains inadmissible hearsay. Subject to said**
24 **objection, admit.**

25 688. In its letter, FDA indicated that BPV still needed to address portions of
26 deficiency 14 (now styled as Question 1). Ex. B, Van Vleet Decl. at ¶ 53.

27 **Objection. This statement contains inadmissible hearsay. Subject to said**
28 **objection, admit that the relied-upon document includes discussion of remaining**

1 **deficiencies in Bard’s Denali IDE application. Deny all other assertions and**
2 **characterizations. This statement mischaracterizes and takes FDA’s discussions**
3 **with Bard about its Denali IDE submission out of context to imply that the FDA**
4 **imposed a mandatory requirement on Bard.**

5 689. In particular, FDA stated that certain of the veterinary findings (dark
6 purple/red mottling on the kidney and liver and very dark coloration of the small intestine)
7 for animal 1451 from the GLP *in-vivo* study represented “a serious safety concern.” Ex.
8 B, Van Vleet Decl. at ¶ 53.

9 **Objection. This statement contains inadmissible hearsay. Subject to said**
10 **objection, admit that the relied-upon document includes discussion of remaining**
11 **deficiencies in Bard’s Denali IDE application. Deny all other assertions and**
12 **characterizations to the extent BPV fails to accurately and adequately summarize**
13 **the findings what led the FDA to conclude that a lack of records raised questions**
14 **about the adequacy of the GLP study and that the findings in animal 1451**
15 **represented “a serious safety concern.” This statement mischaracterizes and takes**
16 **FDA’s discussions with Bard about its Denali IDE submission out of context to imply**
17 **that the FDA imposed a mandatory requirement on Bard.**

18 690. Additionally, FDA required that additional formalin-fixed specimens and
19 slides from all abnormal pathology findings, as well as all gross pathology and
20 histopathology images be sent to a board-certified veterinary pathologist for examination,
21 and then submit the findings to FDA (Questions 1a-1b). Ex. B, Van Vleet Decl. at ¶ 53.

22 **Objection. This statement contains inadmissible hearsay. Subject to said**
23 **objection, admit that the relied-upon document states that the FDA required the**
24 **pathology be sent a board-certified veterinary pathologist and then findings**
25 **submitted to the FDA. Deny all other assertions and characterizations to the extent**
26 **BPV implies this was an additional obligation imposed on BPV beyond what BPV**
27 **should have done as part of the study. This statement mischaracterizes and takes**
28

1 **FDA's discussions with Bard about its Denali IDE submission out of context to imply**
 2 **that the FDA imposed a mandatory requirement on Bard.**

3 691. FDA also asked BPV to provide additional information regarding
 4 biocompatibility testing (Question 2). Ex. B, Van Vleet Decl. at ¶ 53.

5 **Objection. This statement contains inadmissible hearsay. Subject to said**
 6 **objection, admit that the relied-upon document includes discussion of remaining**
 7 **deficiencies in Bard's Denali IDE application. Deny all other assertions and**
 8 **characterizations to the extent BPV implies this was an additional obligation**
 9 **imposed on BPV that was more onerous or above and beyond what would normally**
 10 **be required as part of the IDE submission process and not something that it was**
 11 **required to provide as part of its original submission and was deficient in doing so..**
 12 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
 13 **Denali IDE submission out of context to imply that the FDA imposed a mandatory**
 14 **requirement on Bard.**

15 692. On October 3, 2011, BPV submitted its seventh IDE Supplement
 16 (G11001/S007), which addressed the deficiencies from FDA's September 9, 2011 letter.
 17 Ex. B, Van Vleet Decl. at ¶ 54.

18 **Admit that is what the document says, but deny to extent that it**
 19 **mischaracterizes when the deficiencies were initially identified. The FDA is clear in**
 20 **its September 9, 2011, letter that the deficiencies discussed were deficiencies that**
 21 **were identified in the FDA's February 2, 2011 and remain outstanding because they**
 22 **had not yet been adequately addressed by BPV.**

23 693. In response to FDA's questions about the animal study and animal 1451,
 24 BPV contacted the pathologist and veterinarian who confirmed that the early death of the
 25 animal was not device related (Question 1a). Ex. B, Van Vleet Decl. at ¶ 54.

26 **Objection. This statement contains inadmissible hearsay. Subject to said**
 27 **objection, admit.**
 28

1 694. BPV provided FDA with the board-certified pathologist's report and
2 veterinarian reports that confirmed these opinions. Ex. B, Van Vleet Decl. at ¶ 54.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
4 **objection, admit.**

5 695. In response to FDA's biocompatibility questions (Question 2), BPV
6 provided FDA with the information requested, including describing the extract storage
7 conditions prior to use for various biocompatibility tests (Question 2a), an explanation for
8 weight loss for certain animals in the animal studies (Question 2b), an explanation for the
9 toxicity seen in the cytotoxicity testing (Question 2c), a discussion of reasoning behind the
10 poor mitotic index identified in the chromosomal aberration assay (Question 2d), and a
11 summary of literature for each chemical identified in the exhaustive extraction testing
12 (Question 2e). Ex. B, Van Vleet Decl. at ¶ 54.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit.**

15 696. On November 3, 2011, FDA sent BPV a further revised letter conditionally
16 approving BPV's IDE (G110001) for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 55.

17 **Objection. This statement contains inadmissible hearsay. Subject to said**
18 **objection, admit.**

19 697. In the letter, the agency requested additional information and explanation
20 regarding slight cytotoxicity identified during testing on the delivery system (Question 1).
21 Ex. B, Van Vleet Decl. at ¶ 55.

22 **Admit that the FDA requested this information, but deny to extent that it**
23 **mischaracterizes this information as additional information. The FDA is clear that**
24 **the deficiencies discussed in this letter were deficiencies that were identified in the**
25 **FDA's February 2, 2011 and remain outstanding because they had not yet been**
26 **adequately addressed by BPV.**

1 698. Additionally, the agency stated that the nickel elution levels identified in
2 BPV's exhaustive extraction testing raised "concern for sensitization and
3 carcinogenicity." (Question 2). Ex. B, Van Vleet Decl. at ¶ 55.

4 **Objection. This statement contains inadmissible hearsay. Subject to said**
5 **objection, admit.**

6 699. Accordingly, FDA required BPV to add the following language to the
7 device labeling: "The [DEVICE NAME] consists of nickel-titanium alloy, which is
8 generally considered safe. However, *in vitro* testing has demonstrated that nickel is
9 released from this device. Persons with allergic reactions to nickel may suffer an allergic
10 response to this implant, especially those with a history of metal allergies. Some patients
11 may develop an allergy to nickel if this device is implanted. Certain allergic reactions can
12 be serious. While devices that release nickel are not expected to result in symptoms such
13 as difficulty in breathing or inflammation of the face or throat, if these types of allergic
14 reactions occur, patients should be instructed to seek immediate medical attention. Some
15 forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in
16 animal models. It is unknown whether nickel released from implants will increase a
17 patient's cancer risk." Ex. B, Van Vleet Decl. at ¶ 55.

18 **Objection. This statement contains inadmissible hearsay. Subject to said**
19 **objection, admit that the statement quotes the relied-upon document accurately.**
20 **Deny to the extent BPV implies that this labeling requirement was an additional**
21 **requirement and not required to address a correct a deficiency. This statement**
22 **mischaracterizes and takes FDA's discussions with Bard about its Denali IDE**
23 **submission out of context to imply that the FDA imposed a mandatory requirement**
24 **on Bard.**

25 700. On November 11, 2011, BPV submitted its ninth IDE Supplement
26 (G11001/S009), which addressed the deficiencies from FDA's November 3, 2011 letter.
27 Ex. B, Van Vleet Decl. at ¶ 56.
28

1 **Admit that BPV submitted its ninth IDE Supplement on November 11, 2011,**
2 **but deny to extent that it mischaracterizes that BPV addressed deficiencies that were**
3 **identified in the FDA’s November 3, 2011, letter when this letter merely informed**
4 **BPV that it still needed to address deficiencies identified in the FDA’s February 2,**
5 **2011 that remained outstanding.**

6 701. In response to FDA’s question regarding slight toxicity from the delivery
7 system (Question 1), BPV indicated that its cytotoxicity testing was performed per ISO
8 10993-5:2009, an FDA recognized standard. Ex. B, Van Vleet Decl. at ¶ 56.

9 **Objection. This statement contains inadmissible hearsay. Subject to said**
10 **objection, admit.**

11 702. BPV further explained why the delivery system can be considered non-
12 cytotoxic, given it passed cytotoxicity testing and full biocompatibility testing. Ex. B,
13 Van Vleet Decl. at ¶ 56.

14 **Objection. This statement contains inadmissible hearsay. Subject to said**
15 **objection, admit.**

16 703. BPV included in its response a memorandum from Toxikon, confirming the
17 Denali delivery system is considered non-cytotoxic based on the results of BPV’s testing.
18 Ex. B, Van Vleet Decl. at ¶ 56.

19 **Objection. This statement contains inadmissible hearsay. Subject to said**
20 **objection, admit.**

21 704. In response to FDA’s direction to add certain nickel leaching information to
22 the labeling, BPV agreed to provide the following language to the IFU, per FDA’s
23 request: “The Denali® Filter consists of nickel-titanium alloy, which is generally
24 considered safe. However, *in vitro* testing has demonstrated that nickel is released from
25 this device. Persons with allergic reactions to nickel may suffer an allergic response to
26 this implant, especially those with a history of metal allergies. Some patients may
27 develop an allergy to nickel if this device is implanted. Certain allergic reactions can be
28 serious. While devices that release nickel are not expected to result in symptoms such as

1 difficulty in breathing or inflammation of the face or throat, if these types of allergic
2 reactions occur, patients should be instructed to seek immediate medical attention. Some
3 forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in
4 animal models. It is unknown whether nickel released from implants will increase a
5 patient's cancer risk." Ex. B, Van Vleet Decl. at ¶ 56.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
7 **objection, admit that the relied-upon document is quoted accurately. Deny all other**
8 **assertions and characterizations. This statement mischaracterizes and takes FDA's**
9 **discussions with Bard about its Denali IDE submission out of context to imply that**
10 **the FDA imposed a mandatory requirement on Bard.**

11 705. BPV also provided FDA with a redlined IFU reflecting the changes FDA
12 requested. Ex. B, Van Vleet Decl. at ¶ 56.

13 **Objection. This statement contains inadmissible hearsay. Subject to said**
14 **objection, admit that the relied-upon document included a redlined IFU. Deny all**
15 **other assertions and characterizations. This statement mischaracterizes and takes**
16 **FDA's discussions with Bard about its Denali IDE submission out of context to imply**
17 **that the FDA imposed a mandatory requirement on Bard.**

18 706. On January 31, 2012, BPV provided FDA with its annual IDE Progress
19 Report (G11001/S011). Ex. B, Van Vleet Decl. at ¶ 57.

20 **Admit.**

21 707. The report noted that the Denali® Filter clinical study had 12 active sites
22 and had enrolled 50 patients, 29 of which had reached one or more follow-up points
23 specified in the protocol. Ex. B, Van Vleet Decl. at ¶ 57.

24 **Admit.**

25 708. The report identified all anticipated and unanticipated adverse events, noting
26 that none of the 52 reported events were "recorded as being related or possibly related to
27 the device." Ex. B, Van Vleet Decl. at ¶ 57.

1 **Objection. This statement contains inadmissible hearsay. Subject to said**
2 **objection, admit.**

3 709. In the annual report, BPV noted its future plan to submit a 510(k)
4 submission in 2013, which will include an interim clinical report, and which will seek
5 clearance for “a permanent and retrieval indication once the first 100 patients enrolled
6 complete a six month post-placement with a minimum of 45 retrievals completing a one
7 month post-retrieval visit.” Ex. B, Van Vleet Decl. at ¶ 57.

8 **Admit.**

9 710. On November 13, 2012, BPV submitted its thirteenth IDE Supplement
10 (G11001/S013), which requested modification to the Denali® Filter clinical study
11 protocol. Ex. B, Van Vleet Decl. at ¶ 58.

12 **Admit.**

13 711. Specifically, BPV requested approval to change the study protocol “to state
14 the interim analysis will occur once 50 patients have been retrieved and 65 patients have
15 completed their six month visit. Ex. B, Van Vleet Decl. at ¶ 58.

16 **Admit.**

17 712. The currently approved protocol (Version 8) states the interim analysis will
18 occur once 50 patients have been retrieved and 100 patients have completed their six
19 month visit.” Ex. B, Van Vleet Decl. at ¶ 58.

20 **Admit.**

21 713. BPV noted that it was requesting this change due to a change in physician
22 retrieval practice based on FDA’s initial communication regarding IVC filters and
23 retrieval. Ex. B, Van Vleet Decl. at ¶ 58.

24 **Objection. This statement contains inadmissible hearsay. Subject to said**
25 **objection, admit.**

26 714. BPV further noted that the number of patients required to meet the clinical
27 success of filter placement was re-evaluated and changed from 100 to 65 patients, and that
28 BPV could demonstrate with 95% confidence that the statistical endpoint of clinical

1 success of filter placement can be achieved with 65 patients reaching the six month visit.
2 Ex. B, Van Vleet Decl. at ¶ 58.

3 **Admit.**

4 715. BPV further reiterated its intent to submit a Traditional 510(k) submission
5 to FDA based on the interim analysis and study report. Ex. B, Van Vleet Decl. at ¶ 58.

6 **Admit.**

7 716. On December 4, 2012, BPV provided FDA with a response to FDA's
8 informal questions from November 29, 2012, regarding BPV's requested changes to the
9 Denali® Filter clinical study protocol. Ex. B, Van Vleet Decl. at ¶ 59.

10 **Admit.**

11 717. In response to FDA's request, BPV provided FDA with an update on the
12 status and progress of the Denali® Filter clinical trial. Ex. B, Van Vleet Decl. at ¶ 59.

13 **Admit that the relied-upon document includes discussion of Bard's clinical**
14 **trial for the Denali filter. Deny all other assertions and characterizations. This**
15 **statement mischaracterizes and takes FDA's discussions with Bard about its Denali**
16 **IDE submission out of context to imply that the FDA imposed a mandatory**
17 **requirement on Bard.**

18 718. BPV informed FDA that it had enrolled 162 patients to date. Ex. B, Van
19 Vleet Decl. at ¶ 59.

20 **Objection. This statement contains inadmissible hearsay. Subject to said**
21 **objection, admit.**

22 719. BPV noted technical success of placement was 100%, and clinical success
23 was 97.3% for all subjects. Ex. B, Van Vleet Decl. at ¶ 59.

24 **Objection. This statement contains inadmissible hearsay. Subject to said**
25 **objection, admit.**

26 720. Regarding retrieval, technical success was 100%, with clinical success of
27 98.7%. Ex. B, Van Vleet Decl. at ¶ 59.

1 **Objection. This statement contains inadmissible hearsay. Subject to said**
2 **objection, admit.**

3 721. BPV further noted no reports of filter migration, fracture, or tilt. Ex. B, Van
4 Vleet Decl. at ¶ 59.

5 **Objection. This statement contains inadmissible hearsay. Subject to said**
6 **objection, admit.**

7 722. BPV did report 4 instances of filter penetration, although none were
8 symptomatic. Ex. B, Van Vleet Decl. at ¶ 59.

9 **Objection. This statement contains inadmissible hearsay. Subject to said**
10 **objection, admit that there were 4 reports of filter penetration with none that were**
11 **asymptomatic, but note that the update states “no AEs or clinical sequelae related to**
12 **penetration reported to date.”**

13 723. BPV also explained the statistical rationale for changing the protocol to 65
14 patients. Ex. B, Van Vleet Decl. at ¶ 59.

15 **Objection. This statement contains inadmissible hearsay. Subject to said**
16 **objection, admit.**

17 724. On December 14, 2012, BPV received FDA’s letter approving BPV’s
18 proposed change to the Denali® Filter clinical study protocol as requested in BPV’s
19 thirteenth IDE Supplement (G11001/S013). Ex. B, Van Vleet Decl. at ¶ 60.

20 **Admit that the letter from the FDA approving BPV’s supplement to their IDE**
21 **to change the number of patients from 100 to 65 was received on that date. Deny all**
22 **other assertions and characterizations. This statement mischaracterizes and takes**
23 **FDA’s discussions with Bard about its Denali IDE submission out of context to imply**
24 **that the FDA imposed a mandatory requirement on Bard. The FDA also wrote in**
25 **the letter that it believed (and recommended, but did not require) additional**
26 **modifications to the study. In addition, FDA noted that "approval of an IDE**
27 **application does not ensure that the results of this investigation will provide**
28

1 **reasonable assurance of the safety and effectiveness of your device or assure a**
2 **determination of clearance/approval for your premarket submission.”**

3 725. On January 10, 2013, BPV provided FDA with its annual IDE Progress
4 Report (G11001/S014). Ex. B, Van Vleet Decl. at ¶ 61.

5 **Admit.**

6 726. The report noted that the Denali® Filter clinical study had 23 active sites
7 and had enrolled 171 patients. Ex. B, Van Vleet Decl. at ¶ 61.

8 **Admit.**

9 727. The report identified all anticipated and unanticipated adverse events, noting
10 9 of the reported events were “recorded as being related or possibly related to the device.”
11 Ex. B, Van Vleet Decl. at ¶ 61.

12 **Objection. This statement contains inadmissible hearsay. Subject to said**
13 **objection, admit that this is what the report says, but note that “(2 definitely related;**
14 **7 possibly related)” is omitted from the quote above with no ellipses to indicate the**
15 **omission .**

16 728. In the annual report, BPV noted its future plan to submit a 510(k)
17 submission in 2013, which will include an interim clinical report, and which will seek
18 clearance for “a permanent and retrieval indication once a minimum of 65 patients
19 enrolled complete a six month post-placement with a minimum of 45 retrievals
20 completing a one month post-retrieval visit.” Ex. B, Van Vleet Decl. at ¶ 61.

21 **Admit.**

22 729. On February 7, 2013, FDA sent BPV a letter with questions and requesting
23 additional information regarding BPV’s 2013 annual report for the Denali® Filter clinical
24 trial. Ex. B, Van Vleet Decl. at ¶ 62.

25 **Admit that the letter from the FDA was sent that day as described and the**
26 **letter included a discussion of concerns with Bard’s 2013 annual report. Deny all**
27 **other assertions and characterizations to the extent they imply the FDA was seeking**
28 **additional information above and beyond the requirements of the 510(k) clearance**

1 **process. In the letter, the FDA asks BPV to provide certain information it failed to**
2 **provide or to provide information it had already provided in a more user-friendly**
3 **way.**

4 730. In its letter, FDA identified certain concerns about the adverse events
5 identified by BPV in the study (Question 7). Ex. B, Van Vleet Decl. at ¶ 62.

6 **Objection. This statement contains inadmissible hearsay. Subject to said**
7 **objection, admit.**

8 731. Initially, FDA asked BPV to summarize the data in an illustrative table
9 (Question 7a) to allow for easier interpretation of data. Ex. B, Van Vleet Decl. at ¶ 62.

10 **Objection. This statement contains inadmissible hearsay. Subject to said**
11 **objection, admit.**

12 732. FDA also requested clinical summaries for all patients who died during the
13 study, as well as those with device related adverse events. FDA noted that “these events
14 are of particular interest and should also be described in a separate section as narratives”
15 (Question 7b). Ex. B, Van Vleet Decl. at ¶ 62.

16 **Objection. This statement contains inadmissible hearsay. Subject to said**
17 **objection, admit that the relied-upon document includes discussion of clinical**
18 **summaries of Bard’s patients involved in the clinical study. Deny all other assertions**
19 **and characterizations to the extent they imply the FDA was seeking additional**
20 **information above and beyond the requirements of the 510(k) clearance process.**

21 733. FDA additionally requested a table summarizing all IVC filter-related
22 events, including those related to migration, fracture, and tilting (Question 8). Ex. B, Van
23 Vleet Decl. at ¶ 62.

24 **Admit with clarification that the FDA asked BPV to provide a summary table**
25 **for these secondary endpoints of the study, which is not an extraordinary or**
26 **burdensome request.**

27 734. FDA also requested BPV provided further information regarding subject
28 accountability (Question 1), the number of subjects enrolled per site (Question 2), subject

1 demographics and medical history (Question 3), subjects' indications for placement
2 (Question 4), procedural information for subjects enrolled (Question 5), number of units
3 implanted or returned (Question 6), and retrieval information (Question 9). Ex. B, Van
4 Vleet Decl. at ¶ 62.

5 **Admit that the relied-upon document includes discussion of information on**
6 **BPV's patients enrolled in the clinical study. Deny all other assertions and**
7 **characterizations to the extent they imply the FDA was seeking additional**
8 **information not asking for information that BPV should have provided, but did not.**
9 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
10 **Denali IDE submission out of context to imply that the FDA imposed a mandatory**
11 **requirement on Bard.**

12 735. On February 8, 2013, BPV submitted its Traditional 510(k) submission
13 (K130366) to FDA for the Denali® Filter System -- Femoral and Jugular/Subclavian
14 Delivery Kit. Ex. B, Van Vleet Decl. at ¶ 63.

15 **Admit.**

16 736. In the Denali® 510(k) submission, BPV described for FDA the battery of *in*
17 *vitro* testing conducted by BPV on the Denali® Filter (which FDA had previously
18 reviewed and approved as part of the IDE process), including fatigue resistance, corrosion
19 resistance, cranial migration resistance, caudal migration resistance, penetration resistance
20 (radial strength), tensile, removal force, clot trapping, and other testing. Ex. B, Van Vleet
21 Decl. at ¶ 63.

22 **Admit that BPV described this testing, but deny to the extent the use of**
23 **“battery” is being used to imply these tests are unusual.**

24 737. BPV additionally provided FDA with summaries of this *in vitro* testing. Ex.
25 B, Van Vleet Decl. at ¶ 63.

26 **Admit that BPV provided these summaries, but deny to the extent the use of**
27 **“additionally” is being used to imply providing these summaries with the testing was**
28 **unusual.**

1 738. BPV also described the *in-vivo* animal testing conducted by BPV on the
2 Denali® Filter, and provided FDA with the animal study protocols and reports that were
3 previously provided to FDA as part of the Denali® IDE. Ex. B, Van Vleet Decl. at ¶ 63.

4 **Admit that BPV described the testing and providing the study protocols and**
5 **reports, but deny to the extent this implies it was burdensome and onerous to do so**
6 **or that it was an additional requirement imposed by the FDA.**

7 739. As part of this submission, BPV further provided FDA with all of the
8 Denali® Filter clinical trial IDE submissions. Ex. B, Van Vleet Decl. at ¶ 63.

9 **Admit that BPV provided the clinical trial IDE submissions, but deny to the**
10 **extent this implies it was burdensome and onerous to do so or that it was an**
11 **additional requirement imposed by the FDA.**

12 740. BPV also provided FDA with a summary of the clinical testing from the
13 Denali® Trial. Ex. B, Van Vleet Decl. at ¶ 63.

14 **Admit that BPV provided a summary of the clinical testing, but deny to the**
15 **extent this implies it was burdensome and onerous to do so or that it was an**
16 **additional requirement imposed by the FDA.**

17 741. It noted that 175 patients had been enrolled at 20 sites. Ex. B, Van Vleet
18 Decl. at ¶ 63.

19 **Admit.**

20 742. It further noted there were no findings of caval occlusion, filter fracture,
21 migration (cranial or caudal), or tilt. Ex. B, Van Vleet Decl. at ¶ 63.

22 **Admit.**

23 743. It noted 2 cases of symptomatic PE and 5 cases of asymptomatic
24 penetration. Ex. B, Van Vleet Decl. at ¶ 63.

25 **Admit.**

26 744. It further noted a retrieval success rate of 97.7% (2 unsuccessful retrievals).
27 Ex. B, Van Vleet Decl. at ¶ 63.

28 **Admit.**

1 745. BPV additionally provided FDA with the interim clinical study report from
2 the Denali® Filter trial. Ex. B, Van Vleet Decl. at ¶ 63.

3 **Admit that BPV provided the interim clinical study report, but deny to the**
4 **extent this implies it was burdensome and onerous to do so or that it was an**
5 **additional requirement imposed by the FDA.**

6 746. On March 1, 2013, BPV provided FDA with the company's formal response
7 to the agency's February 7, 2013 questions regarding BPV's 2013 annual report for the
8 Denali® Filter clinical trial. Ex. B, Van Vleet Decl. at ¶ 64.

9 **Admit that BPV provided a formal response on February 7, 2013 to the FDA's**
10 **questions. Deny all other assertions and characterizations to the extent they imply**
11 **the FDA was seeking additional information above and beyond the requirements of**
12 **the 510(k) clearance process. Instead, the FDA asks BPV to provide certain**
13 **information it failed to provide or to provide information it had already provided in**
14 **a more user-friendly way.**

15 747. To address FDA's concerns regarding adverse events, BPV provided FDA
16 with an illustrative table that summarized the adverse event data (Question 7a). Ex. B,
17 Van Vleet Decl. at ¶ 64.

18 **Objection. This statement contains inadmissible hearsay. Subject to said**
19 **objection, admit.**

20 748. BPV also provided FDA with clinical summaries for all patients who died
21 during the study, as well as those with device related adverse events (Question 7b). Ex. B,
22 Van Vleet Decl. at ¶ 64.

23 **Admit.**

24 749. BPV further provided a table summarizing all IVC filter-related events,
25 including related to migration, fracture, and tilting (Question 8). Ex. B, Van Vleet Decl.
26 at ¶ 64.

1 **Admit with clarification that the FDA asked BPV to provide a summary table**
2 **for these secondary endpoints of the study, which is not an extraordinary or**
3 **burdensome request.**

4 750. Finally, BPV provided the additional information FDA requested, including
5 regarding subject accountability (Question 1), the number of subjects enrolled per site
6 (Question 2), subject demographics and medical history (Question 3), subjects'
7 indications for placement (Question 4), procedural information for subjects enrolled
8 (Question 5), number of units implanted or returned (Question 6), and retrieval
9 information (Question 9). Ex. B, Van Vleet Decl. at ¶ 64.

10 **Admit that BPV provided this information. Deny to the extent it implies the**
11 **FDA was seeking additional information additional information above and beyond**
12 **the requirements of the 510(k) clearance process.**

13 751. On March 14-19, 2013, FDA and BPV exchanged a series of emails
14 regarding FDA's questions concerning BPV's Denali® Filter 510(k) Submissions. Ex. B,
15 Van Vleet Decl. at ¶ 65.

16 **Admit.**

17 752. Specifically, in a March 14 email, FDA asked for information regarding the
18 clinical events committee and data safety monitoring board for the clinical trial (Question
19 1), a copy of the proposed patient brochure (Question 2), and a copy of the proposed
20 patient implant card (Question 3). Ex. B, Van Vleet Decl. at ¶ 65.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, admit that the FDA requested this information. Deny all other assertions**
23 **and characterizations to the extent they imply the FDA was seeking additional**
24 **information above and beyond the requirements of the 510(k) clearance process.**
25 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
26 **Denali IDE submission out of context to imply that the FDA imposed a mandatory**
27 **requirement on Bard.**

1 753. BPV provided responses to FDA's questions that same day. Ex. B, Van
2 Vleet Decl. at ¶ 65.

3 **Admit.**

4 754. In follow-up on the same day, FDA required that BPV make certain changes
5 regarding MR compatibility for the patient implant card, and to add certain information
6 regarding the image artifact that was observed. Ex. B, Van Vleet Decl. at ¶ 65.

7 **Admit that the FDA requested these changes. Deny all other assertions and**
8 **characterizations to the extent they imply the FDA was seeking additional**
9 **information above and beyond the requirements of the 510(k) clearance process.**
10 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
11 **Denali filter out of context to imply that the FDA imposed a mandatory requirement**
12 **on Bard.**

13 755. BPV provided responses to FDA's follow-up questions on March 18, 2013.
14 Ex. B, Van Vleet Decl. at ¶ 65.

15 **Admit.**

16 756. Over a series of emails on March 18 and 19, BPV and FDA corresponded to
17 ensure BPV's changes to the labeling met FDA's requirements. Ex. B, Van Vleet Decl. at
18 ¶ 65.

19 **Objection. This statement contains inadmissible hearsay. Subject to said**
20 **objection, admit that BPV and FDA corresponded on March 18 and 19 regarding**
21 **changes to labeling. Deny all other assertions and characterizations to the extent**
22 **they imply the FDA was seeking additional information above and beyond the**
23 **requirements of the 510(k) clearance process. This statement mischaracterizes and**
24 **takes FDA's discussions with Bard about its Denali filter submissions out of context**
25 **to imply that the FDA imposed mandatory requirements on Bard.**

26 757. On April 6, 2013, FDA sent BPV an email requesting additional information
27 it deemed necessary to determine whether it could clear the Denali® Filter. Ex. B, Van
28 Vleet Decl. at ¶ 66.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the relied-upon document includes discussion of Bard's Denali 510(k) application. Deny all other assertions and characterizations. This statement mischaracterizes and takes FDA's discussions with Bard about its Denali filter submissions out of context to imply that the FDA imposed mandatory requirements on Bard. The FDA was requesting this information because it could not "determine if the device is substantially equivalent to a legally marketed predicate device" based on the information provided by Bard. This is information that BPV should have provided with its 510(k) notification, not additional information above and beyond the requirements of the 510(k) clearance process.

758. Specifically, FDA required BPV to make certain changes to the indication for use statement that accompanies the labeling (Question 1), changes to the labeling with regard to latex labeling (Question 2), and to address FDA's comments about BPV's draft IFU and patient brochures (Question 8). Ex. B, Van Vleet Decl. at ¶ 66.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the relied-upon document includes discussion of Bard's Denali 510(k) application. Deny all other assertions and characterizations. This statement mischaracterizes and takes FDA's discussions with Bard about its Denali filter submissions out of context to imply that the FDA imposed mandatory requirements on Bard. The FDA was requesting this information because it could not "determine if the device is substantially equivalent to a legally marketed predicate device" based on the information provided by Bard. This is information that BPV should have provided with its 510(k) notification, not additional information above and beyond the requirements of the 510(k) clearance process.

759. FDA also requested additional information regarding the results of sterilization testing (Question 3). Ex. B, Van Vleet Decl. at ¶ 66.

Objection. This statement contains inadmissible hearsay. Subject to said objection, admit that the relied-upon document includes discussion of Bard's Denali

1 **510(k) application. Deny all other assertions and characterizations. This statement**
2 **mischaracterizes and takes FDA’s discussions with Bard about its Denali filter**
3 **submissions out of context to imply that the FDA imposed mandatory requirements**
4 **on Bard. The FDA was requesting this information because it could not “determine**
5 **if the device is substantially equivalent to a legally marketed predicate device” based**
6 **on the information provided by Bard. This is information that BPV should have**
7 **provided with its 510(k) notification, not additional information above and beyond**
8 **the requirements of the 510(k) clearance process.**

9 760. FDA also requested information regarding the color additives in the delivery
10 system (Question 4). Ex. B, Van Vleet Decl. at ¶ 66.

11 **Objection. This statement contains inadmissible hearsay. Subject to said**
12 **objection, admit that the relied-upon document includes discussion of Bard’s Denali**
13 **510(k) application. Deny all other assertions and characterizations. This statement**
14 **mischaracterizes and takes FDA’s discussions with Bard about its Denali filter**
15 **submissions out of context to imply that the FDA imposed mandatory requirements**
16 **on Bard. The FDA was requesting this information because it could not “determine**
17 **if the device is substantially equivalent to a legally marketed predicate device” based**
18 **on the information provided by Bard. This is information that BPV should have**
19 **provided with its 510(k) notification, not additional information above and beyond**
20 **the requirements of the 510(k) clearance process.**

21 761. FDA also requested explanation regarding calculation of secondary
22 endpoints (Question 6), and regarding details on the method to obtain p-values of primary
23 study outcome homogeneity among study sites (Question 7). Ex. B, Van Vleet Decl. at ¶
24 66.

25 **Objection. This statement contains inadmissible hearsay. Subject to said**
26 **objection, admit that the relied-upon document includes discussion of Bard’s Denali**
27 **510(k) application. Deny all other assertions and characterizations. This statement**
28 **mischaracterizes and takes FDA’s discussions with Bard about its Denali filter**

1 submissions out of context to imply that the FDA imposed mandatory requirements
2 on Bard. The FDA was requesting this information because it could not “determine
3 if the device is substantially equivalent to a legally marketed predicate device” based
4 on the information provided by Bard. This is information that BPV should have
5 provided with its 510(k) notification, not additional information above and beyond
6 the requirements of the 510(k) clearance process.

7 762. On April 15, 2013, BPV sent FDA an email providing responses to the
8 agency’s April 6, 2013 questions. Ex. B, Van Vleet Decl. at ¶ 67.

9 **Admit.**

10 763. Regarding FDA’s requested changes to labeling, BPV agreed to make the
11 changes (Questions 1 & 2). Ex. B, Van Vleet Decl. at ¶ 67.

12 **Objection.** This statement contains inadmissible hearsay. Subject to said
13 objection, admit that the relied-upon document includes discussion of Bard’s Denali
14 510(k) application and labeling. Deny all other assertions and characterizations to
15 the extent they imply the FDA was imposing additional mandatory requirements on
16 BPV above and beyond the requirements of the 510(k) clearance process. This
17 statement mischaracterizes and takes FDA’s discussions with Bard about its Denali
18 filter submissions out of context to imply that the FDA imposed mandatory
19 requirements on Bard. The FDA was requesting this information because it could
20 not “determine if the device is substantially equivalent to a legally marketed
21 predicate device” based on the information provided by Bard.

22 764. BPV also provided FDA with additional information regarding the results of
23 sterilization testing (Question 3). Ex. B, Van Vleet Decl. at ¶ 67.

24 **Admit BPV provided this information. Deny all other assertions and**
25 **characterizations to extent they imply the FDA was requiring this information above**
26 **and beyond the requirements of the 510(k) clearance process. The FDA was**
27 **requesting this information because it could not “determine if the device is**
28 **substantially equivalent to a legally marketed predicate device” based on the**

1 **information provided by Bard. This is information that BPV should have provided**
2 **with its 510(k) notification.**

3 765. BPV also provided FDA with information regarding the color additives in
4 the delivery system (Question 4). Ex. B, Van Vleet Decl. at ¶ 67.

5 **Admit BPV provided this information. Deny all other assertions and**
6 **characterizations to extent they imply the FDA was requiring this information above**
7 **and beyond the requirements of the 510(k) clearance process. This statement**
8 **mischaracterizes and takes FDA’s discussions with Bard about its Denali filter**
9 **submissions out of context to imply that the FDA imposed mandatory requirements**
10 **on Bard. The FDA was requesting additional information because it could not**
11 **“determine if the device is substantially equivalent to a legally marketed predicate**
12 **device” based on the information provided by Bard. This is information that BPV**
13 **should have provided with its 510(k) notification.**

14 766. BPV also provided FDA with explanations regarding lack of need for
15 sensitivity analysis for the clinical results (Question 5), regarding calculation of secondary
16 endpoints (Question 6), and regarding details on the method to obtain p-values of primary
17 study outcome homogeneity among study sites (Question 7). Ex. B, Van Vleet Decl. at ¶
18 67.

19 **Admit BPV provided these explanations. Deny all other assertions and**
20 **characterizations to extent they imply the FDA was requiring additional information**
21 **above and beyond the requirements of the 510(k) clearance process. This statement**
22 **mischaracterizes and takes FDA’s discussions with Bard about its Denali filter**
23 **submissions out of context to imply that the FDA imposed mandatory requirements**
24 **on Bard. The FDA was requesting this information because it could not “determine**
25 **if the device is substantially equivalent to a legally marketed predicate device” based**
26 **on the information provided by Bard. This is information that BPV should have**
27 **provided with its 510(k) notification.**
28

1 767. On April 24, 2013, BPV sent FDA an email providing further responses
2 regarding Question 4 and the colorant information as identified in FDA's April 6, 2013
3 email. Ex. B, Van Vleet Decl. at ¶ 68.

4 **Admit that BPV provided these responses. Deny all other assertions and**
5 **characterizations to extent they imply the FDA was requiring this information above**
6 **and beyond the requirements of the 510(k) clearance process. This statement**
7 **mischaracterizes and takes FDA's discussions with Bard about its Denali filter**
8 **submissions out of context to imply that the FDA imposed mandatory requirements**
9 **on Bard. The FDA was requesting additional information because it could not**
10 **"determine if the device is substantially equivalent to a legally marketed predicate**
11 **device" based on the information provided by Bard. This is information that BPV**
12 **should have provided with its 510(k) notification.**

13 768. On May 2, 2013, FDA Sent BPV an email asking the company to address
14 additional questions related to the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 69.

15 **Admit that BPV sent an email asking BPV to address questions. Deny all other**
16 **assertions and characterizations to extent they imply the FDA was requiring**
17 **additional information above and beyond the requirements of the 510(k) clearance**
18 **process.**

19 769. In particular, FDA noted it was still waiting to receive colorant information
20 from Bard's suppliers. FDA noted that without such information, "FDA cannot make a
21 regulatory decision for [BPV's] submission" (Question 1). Ex. B, Van Vleet Decl. at ¶
22 69.

23 **Objection. This statement contains inadmissible hearsay. Subject to said**
24 **objection, admit that the FDA noted that it was still waiting for the information and**
25 **could not make a regulatory decision without it. Deny all other assertions and**
26 **characterizations to extent they imply the FDA was requiring additional information**
27 **above and beyond the requirements of the 510(k) clearance process.**
28

1 770. FDA further requested clarification and additional information regarding the
2 rate of recurrent PE identified in the study per the study protocol (Question 2), and the
3 rates for worsening DVT, fracture, and migration (Question 3). Ex. B, Van Vleet Decl. at
4 ¶ 69.

5 **Admit that the FDA required clarification regarding these issues. Deny all**
6 **other assertions and characterizations to extent they imply the FDA was requiring**
7 **additional information above and beyond the requirements of the 510(k) clearance**
8 **process. For example, with Question 2, the FDA is asking BPV to justify the use of a**
9 **certain denominator for the calculation of the rate of recurrent PE because the FDA**
10 **is clearly concerned about the possibility that BPV's choice may have led to biased**
11 **results. This statement mischaracterizes and takes FDA's discussions with Bard**
12 **about its Denali filter submissions out of context to imply that the FDA imposed**
13 **mandatory requirements on Bard. The FDA was requesting additional information**
14 **to determine if the Denali was substantially equivalent to the predicate device so it**
15 **could be cleared through the 510(k) process and could not do so based on the**
16 **information provided by Bard.**

17 771. Finally, FDA required BPV to address and make certain changes to the IFU
18 as indicated in a redlined/commented IFU provided by FDA (Question 4). Ex. B, Van
19 Vleet Decl. at ¶ 69.

20 **Objection. This statement contains inadmissible hearsay. Subject to said**
21 **objection, admit that the relied-upon document includes discussion of Bard's Denali**
22 **510(k) application. Deny all other assertions and characterizations to extent they**
23 **imply the FDA was requiring additional information above and beyond the**
24 **requirements of the 510(k) clearance process. This statement mischaracterizes and**
25 **takes FDA's discussions with Bard about its Denali filter submissions out of context**
26 **to imply that the FDA imposed mandatory requirements on Bard.**

27 772. On May 6, 2013, BPV sent FDA an email providing responses (with
28 attachments) to FDA's May 2, 2013 email. Ex. B, Van Vleet Decl. at ¶ 70.

1 **Admit.**

2 773. Regarding colorant information, BPV provided additional information as
3 requested by FDA (Question 1). Ex. B, Van Vleet Decl. at ¶ 70.

4 **Admit BPV provided this information to the FDA. Deny all other assertions**
5 **and characterizations to extent they imply the FDA was requiring additional**
6 **information above and beyond the requirements of the 510(k) clearance process.**

7 774. Regarding the rate for recurrent PE, BPV provided FDA with alternative
8 methods for calculating the denominator to derive a rate (Question 2) and asked FDA
9 which one FDA preferred. BPV also provided clarification regarding the denominator for
10 the rates for worsening DVT, fracture, and migration (Question 3). Ex. B, Van Vleet
11 Decl. at ¶ 70.

12 **Admit. Deny all other assertions and characterizations to extent they imply**
13 **the FDA was requiring additional information above and beyond the requirements**
14 **of the 510(k) clearance process.**

15 775. Finally, BPV addressed FDA's questions and comments regarding the IFU
16 and provided redlined proposed revised IFUs (Question 4). Ex. B, Van Vleet Decl. at ¶
17 70.

18 **Admit BPV addressed the FDA's questions and comments. Deny all other**
19 **assertions and characterizations to extent they imply the FDA was requiring**
20 **additional information above and beyond the requirements of the 510(k) clearance**
21 **process.**

22 776. On May 8, 2013, FDA and BPV had a telephone call to discuss rates
23 identified in the IFU, after which the company provided FDA with a follow-up email and
24 revised clinical section from the IFU per the conversation. Ex. B, Van Vleet Decl. at ¶ 71.

25 **Admit that the FDA had a telephone call to discuss these things. Deny all other**
26 **assertions and characterizations to extent they imply the FDA was requiring**
27 **additional information above and beyond the requirements of the 510(k) clearance**
28 **process.**

1 777. On May 10, 2013, FDA sent BPV an email indicating that BPV's proposed
2 revisions to the Denali® Filter IFU "adequately addresses FDA's comments." Ex. B, Van
3 Vleet Decl. at ¶ 72.

4 **Admit.**

5 778. In its email, FDA additionally requested that BPV make certain changes to
6 the 510(k) summary for the Denali® Filter. Ex. B, Van Vleet Decl. at ¶ 72.

7 **Objection. This statement contains inadmissible hearsay. Subject to said**
8 **objection, admit that the FDA requested that BPV make certain changes. Deny all**
9 **other assertions and characterizations to extent they imply the FDA was requiring**
10 **additional information above and beyond the requirements of the 510(k) clearance**
11 **process. This statement mischaracterizes and takes FDA's discussions with Bard**
12 **about its Denali filter submissions out of context to imply that the FDA imposed**
13 **mandatory requirements on Bard. The FDA was requesting additional information**
14 **to determine if the Denali was substantially equivalent to the predicate device so it**
15 **could be cleared through the 510(k) process and could not do so based on the**
16 **information provided by Bard.**

17 779. Specifically, FDA requested BPV to update the indication for use statement
18 (Question 1), asked BPV to add a description of the differences between the predicate and
19 subject devices (Question 2), asked BPV to add a statement that biocompatibility testing
20 had been conducted (Question 3), asked BPV to add a section describing the animal
21 studies performed (Question 4), asked BPV to update the clinical study section (Question
22 5), and asked BPV to remove any confidentiality footer (Question 6). Ex. B, Van Vleet
23 Decl. at ¶ 72.

24 **Admit that the FDA made these requests of BPV. Deny all other assertions**
25 **and characterizations to extent they imply the FDA was requiring additional**
26 **information above and beyond the requirements of the 510(k) clearance process.**
27 **This statement mischaracterizes and takes FDA's discussions with Bard about its**
28 **Denali filter submissions out of context to imply that the FDA imposed mandatory**

1 requirements on Bard. The FDA was requesting additional information to determine
2 if the Denali was substantially equivalent to the predicate device so it could be
3 cleared through the 510(k) process and could not do so based on the information
4 provided by Bard.

5 780. On May 10, 2013, BPV sent FDA an email revising the 510(k) summary
6 and indications for use statement per FDA's request from the same day. Ex. B, Van Vleet
7 Decl. at ¶ 73.

8 **Admit BPV sent FDA an email revising the 510(k) summary and IFU**
9 **statement. Deny all other assertions and characterizations to extent they imply the**
10 **FDA was requiring additional information above and beyond the requirements of**
11 **the 510(k) clearance process.**

12 781. On May 14, 2013, BPV and FDA exchanged emails regarding the animal
13 study description in the 510(k) summary. Ex. B, Van Vleet Decl. at ¶ 74.

14 **Admit.**

15 782. Specifically, FDA asked for, and BPV provided, a few additional sentences
16 describing the animal study results. Ex. B, Van Vleet Decl. at ¶ 74.

17 **Admit that the FDA asked for a few sentences describing the study results.**
18 **Deny all other assertions and characterizations to extent they imply the FDA was**
19 **requiring additional information above and beyond the requirements of the 510(k)**
20 **clearance process. This statement mischaracterizes and takes FDA's discussions**
21 **with Bard about its Denali filter submissions out of context to imply that the FDA**
22 **imposed mandatory requirements on Bard. The FDA was requesting additional**
23 **information to determine if the Denali was substantially equivalent to the predicate**
24 **device so it could be cleared through the 510(k) process and could not do so based on**
25 **the information provided by Bard.**

26 783. On May 15, 2013, FDA sent BPV a letter clearing the Denali® Filter
27 System -- Femoral and Jugular/Subclavian Delivery Kit (K130366). Ex. B, Van Vleet
28 Decl. at ¶ 75.

1 **Admit.**

2 784. On January 30, 2014, BPV provided FDA with its annual IDE Progress
3 Report (G11001/S017). Ex. B, Van Vleet Decl. at ¶ 76.

4 **Admit.**

5 785. The report noted that the Denali® Filter clinical study had 19 active sites
6 and had enrolled 200 patients from 21 sites after 23 sites were accepted (4 sites were
7 closed, two of which enrolled zero patients). Ex. B, Van Vleet Decl. at ¶ 76.

8 **Objection. This statement contains inadmissible hearsay. Subject to said**
9 **objection, admit.**

10 786. The report included information regarding subject demographics and
11 indications for placement. Ex. B, Van Vleet Decl. at ¶ 76.

12 **Admit.**

13 787. It also provided information regarding placement and retrieval procedures.
14 Ex. B, Van Vleet Decl. at ¶ 76.

15 **Admit.**

16 788. The report identified all anticipated and unanticipated adverse events, noting
17 10 of the reported events were “recorded as being related or possibly related to the
18 device.” Ex. B, Van Vleet Decl. at ¶ 76.

19 **Objection. This statement contains inadmissible hearsay. Subject to said**
20 **objection, admit that this is what the report says, but note that “(2 definitely related;**
21 **8 possibly related)” is omitted from the quote above with no ellipses to indicate the**
22 **omission. Deny as to the relied-upon document accurately representing “all**
23 **anticipated and unanticipated adverse events.”**

24 789. Notably, the report notes zero instances of filter tilt, fracture, embolization,
25 or migration. Ex. B, Van Vleet Decl. at ¶ 76.

26 **Objection. This statement contains inadmissible hearsay. Subject to said**
27 **objection, admit that the relied-upon document is accurately described.**

1 790. However, the report does note 3 instances of caval penetration at placement,
2 and 2 at retrieval. Ex. B, Van Vleet Decl. at ¶ 76.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
4 **objection, admit that the relied-upon document is accurately described.**

5 791. On November 7, 2014, BPV submitted a Special 510(k) for the Denali®
6 Filter System -- Femoral and Jugular/Subclavian Delivery Kit (K143208). Ex. B, Van
7 Vleet Decl. at ¶ 77.

8 **Admit.**

9 792. The purpose of this 510(k) was to gain clearance for certain changes to the
10 Denali® Filter delivery system. There were no changes to the filter itself as part of this
11 submission. Ex. B, Van Vleet Decl. at ¶ 77.

12 **Objection. This statement lacks foundation. Subject to said objection, deny.**
13 **No exhibit supports this characterization of the purpose of the submission. This**
14 **“fact” is actually an opinion about why Bard was providing this information.**

15 793. In the submission, BPV described the *in-vitro* testing conducted. Ex. B,
16 Van Vleet Decl. at ¶ 77.

17 **Admit.**

18 794. FDA cleared this minor change to the delivery kit on December 9, 2014.
19 Ex. B, Van Vleet Decl. at ¶ 77.

20 **Admit.**

21 795. On January 30, 2015, BPV provided FDA with its annual IDE Progress
22 Report (G11001/R003). Ex. B, Van Vleet Decl. at ¶ 78.

23 **Admit.**

24 796. The report noted that the Denali® Filter clinical study had 4 active sites, had
25 enrolled 200 patients from 21 sites after 23 sites were accepted, and had closed 19 sites.
26 Ex. B, Van Vleet Decl. at ¶ 78.

27 **Admit.**

1 797. The report included information regarding subject demographics and
2 indications for placement. Ex. B, Van Vleet Decl. at ¶ 78.

3 **Admit.**

4 798. It also provided information regarding placement and retrieval procedures.
5 Ex. B, Van Vleet Decl. at ¶ 78.

6 **Admit.**

7 799. The report identified all anticipated and unanticipated adverse events, noting
8 11 of the reported events were “recorded as being related or possibly related to the
9 device.” Ex. B, Van Vleet Decl. at ¶ 78.

10 **Objection. This statement contains inadmissible hearsay. Subject to said**
11 **objection, admit that this is what the report says, but note that “(2 definitely related;**
12 **9 possibly related)” is omitted from the quote above with no ellipses to indicate the**
13 **omission. Deny as to the relied-upon document accurately representing “all**
14 **anticipated and unanticipated adverse events.”**

15 800. Notably, the report identified zero instances of filter tilt, fracture,
16 embolization, or migration. Ex. B, Van Vleet Decl. at ¶ 78.

17 **Objection. This statement contains inadmissible hearsay. Subject to said**
18 **objection, admit that the relied-upon document is accurately described.**

19 801. However, the report does note 3 instances of caval penetration at placement,
20 and 2 at retrieval. Ex. B, Van Vleet Decl. at ¶ 78.

21 **Objection. This statement contains inadmissible hearsay. Subject to said**
22 **objection, admit that the relied-upon document is accurately described.**

23 802. On January 29, 2016, BPV provided FDA with its Final Annual Report
24 (G110001/R005). Ex. B, Van Vleet Decl. at ¶ 79.

25 **Admit.**

26 803. This final report documents the clinical investigation of 200 subjects
27 enrolled under IDE G110001 who underwent placement and, in a subset of cases, retrieval
28

1 of the Bard Denali® Filter. It noted that patient enrollment began on June 23, 2011 and
 2 follow-up ended on March 30, 2015. Ex. B, Van Vleet Decl. at ¶ 79.

3 **Objection. This statement contains inadmissible hearsay. Subject to said**
 4 **objection, admit that the relied-upon document is accurately described.**

5 804. The final report included summaries of the number of investigators,
 6 enrollment information, subject demographics, indications for placement, results,
 7 placement and removal procedures. Ex. B, Van Vleet Decl. at ¶ 79.

8 **Admit that the relied-upon document is accurately described.**

9 805. It also included a report of all anticipated and unanticipated adverse events,
 10 noting 11 of the reported events were “recorded as being related or possibly related to the
 11 device.” Ex. B, Van Vleet Decl. at ¶ 79.

12 **Objection. This statement contains inadmissible hearsay. Subject to said**
 13 **objection, admit that this is what the report says, but note that “(2 definitely related;**
 14 **9 possibly related)” is omitted from the quote above with no ellipses to indicate the**
 15 **omission. Deny as to the relied-upon document accurately representing “all**
 16 **anticipated and unanticipated adverse events.”**

17 806. Notably, the report notes zero instances of filter fracture, embolization, or
 18 migration. Ex. B, Van Vleet Decl. at ¶ 79.

19 **Objection. This statement contains inadmissible hearsay. Subject to said**
 20 **objection, admit that the relied-upon document is accurately described.**

21 807. However, the report does note 3 instances of caval penetration at placement,
 22 and 2 at retrieval. Ex. B, Van Vleet Decl. at ¶ 79.

23 **Objection. This statement contains inadmissible hearsay. Subject to said**
 24 **objection, admit that the relied-upon document is accurately described.**

25 808. The report also included a list of all serious adverse events, and summaries
 26 of all patient deaths. Ex. B, Van Vleet Decl. at ¶ 79.

27 **Objection. This statement contains inadmissible hearsay. Subject to said**
 28 **objection, admit that the relied-upon document is accurately described.**

1 809. On February 16, 2016, FDA sent BPV an email with a few questions
2 regarding BPV's final IDE and annual report. Ex. B, Van Vleet Decl. at ¶ 80.

3 **Admit that the FDA sent BPV an email with a few questions. Deny to extent it**
4 **implies the FDA was asking for additional information when in fact the FDA was**
5 **asking for confirmation that it is final IDE report and clarification regarding**
6 **discrepancies involving adverse event reporting.**

7 810. FDA requested clarification that BPV's report was a final IDE report
8 (Question 1). Ex. B, Van Vleet Decl. at ¶ 80.

9 **Admit.**

10 811. FDA also requested clarification regarding the summaries of patient death
11 during the study (Question 2). Ex. B, Van Vleet Decl. at ¶ 80.

12 **Admit that the FDA requested clarification regarding summaries of patient**
13 **death during the study. Deny all other assertions and characterizations to extent**
14 **they imply the FDA was requiring additional information above and beyond the**
15 **requirements of the 510(k) clearance process. The FDA was requesting a**
16 **clarification of a discrepancy in the report as to whether a death was possibly related**
17 **to the device so it could be cleared through the 510(k) process.**

18 812. FDA also requested clarification regarding filter related events (Question 3).
19 Ex. B, Van Vleet Decl. at ¶ 80.

20 **Deny. The FDA requested confirmation that filter related events in Table 5**
21 **were tracked throughout the follow up period or “[i]n other words, please confirm**
22 **that no filter fractures, migration or embolization were seen in the entire 200 subject**
23 **study.”**

24 813. On February 18, 2016, BPV provided FDA with an email responding to
25 FDA's February 16, 2016 questions. Ex. B, Van Vleet Decl. at ¶ 81.

26 **Admit BPV sent an email responding. Deny all other assertions and**
27 **characterizations to extent they imply the FDA was requiring additional information**
28

1 **above and beyond the standard requirements on all device manufacturer with**
2 **regard to an IDE.**

3 814. In the response, BPV clarified that it had submitted a final IDE report and
4 was going to request closure of the IDE via a separate submission. FDA indicated in
5 response that this was not necessary (Question 1). Ex. B, Van Vleet Decl. at ¶ 81.

6 **Admit.**

7 815. Additionally, BPV provided a revised patient death summary to identify that
8 one patient death was adjudicated as “possibly related” to the device (Question 2), and
9 two other revised patient death summaries to clarify that they were not related to the
10 device. Ex. B, Van Vleet Decl. at ¶ 81.

11 **Admit that the relied-upon document is accurately described.**

12 816. Finally, BPV confirmed that there were no fractures, migrations, or
13 embolizations reported for any of the 200 subjects of the study regardless of follow-up
14 time. Ex. B, Van Vleet Decl. at ¶ 81.

15 **Admit that the relied-upon document is accurately described.**

16 817. On February 26, 2016, FDA sent BPV a letter acknowledging the
17 completion of the Denali® Filter clinical investigation. Ex. B, Van Vleet Decl. at ¶ 82.

18 **Admit.**

19 818. Per the FDA’s letter, FDA considered BPV’s IDE application closed. Ex.
20 B, Van Vleet Decl. at ¶ 82.

21 **Admit.**

22 **RESPECTFULLY SUBMITTED** this 1st day of September, 2017.

23 **GALLAGHER & KENNEDY, P.A.**

24 By: /s/ Mark S. O’Connor
25 Mark S. O’Connor
26 2575 East Camelback Road
27 Phoenix, Arizona 85016-9225
28

LOPEZ McHUGH LLP

Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

HEAVISIDE REED ZAIC

Julia Reed Zaic, Esq. (CA Bar No. 224671)
(admitted *pro hac vice*)
Laura Smith, Esq. (CA Bar No. 313879)
(admitted *pro hac vice*)
312 Broadway, Suite 203
Laguna Beach, California 92660

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti

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